
From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/16/2020 9:09:24 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: UK Therapeutics Prioritization List and Process
Attachments: XYZ candidate agent list as of 4-15-20.xlsx; ACCORD product selection process 4-15-20 deid.pptx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup Members,

Please see attached a slightly anonymized list of therapeutics considered by the science group in the UK that we spoke about. They have indicated their permission for us to share this with this group only, to aid in your deliberations about our parallel agent prioritization efforts, but with the express request that you not copy or distribute this beyond the group on this email. We have been asked to emphasize that this is a work in progress and does not represent the end of a considered or consolidated process, nor has that process or these results been formally adopted or endorsed by any UK government agency or organization. We will work with Deloitte to incorporate such information as you think valuable into the larger inventory of potential agents for prioritization that we have been working on with you, by the way.

FYI, we have asked for an update on the protocol that would be associated with testing such agents as may be selected, and have been told that is not sufficiently finalized to be shared yet. We will let you and the MP Subgroup know when we have something to share there.

Thank you all for your help in adhering to our collaboration guidelines from that team.

Kind regards,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/15/2020 7:46:21 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I just sent out the same message with these names now in the bcc line. So everyone will have received it now.

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 15, 2020 2:08 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

Francis – the following emails were missing from the list that went out, please see 8 emails listed below.

Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) (b) (6)
Kim, Elizabeth <el (b) (6)>
Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
Paul, Steve <(b) (6)>
Payne, David <david.j. (b) (6)>
Plump, (b) (6)
Santos, Nancy (b) (6) >
Shen, Yuan Li (FDA/CDER) <(b) (6)>

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 15, 2020 11:39 AM
To: Melencio, Cheryl (FNIH) [T] (b) (6) Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

From: Melencio, Cheryl (FNIH) [T] (b) (6) >
Sent: Wednesday, April 15, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6)
Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Bright, Rick (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) >; Corey, Larry (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael (b) (6) >; Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> >; Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Frankowski, David <(b) (6)> >; Hudson, Thomas <(b) (6)> >; James, Stephanie (FNIH)

[T] (b) (6) >; Klock, Kevin (FNIH) [T] < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6)
 Marks, Peter (FDA/CBER) (b) (6) >; Marston, Hilary (NIH/NIAID) [E] (b) (6)
 Mascola, John < (b) (6) Meeker, David (b) (6) Menetski, Joseph (FNIH) [T]
 (b) (6) ; Pangalos, Mene < (b) (6) >; Pao, William (b) (6) >;
 Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6) >; Plump, Andy
 (b) (6) ; Rasi, Guido (b) (6) Reed, John < (b) (6) Rouse,
 Doris (b) (6) Santos, Michael (FNIH) [T] (b) (6) >; Skovronsky, Daniel
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) Stoffels, Paul
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Tsai, John
 < (b) (6) Vessey, Rupert (b) (6) >; Virgin, Skip (b) (6) Wholley, David
 (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) >; Young, John
 (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) ; Bascles, Lionel
 (b) (6) Cohen, Myron (b) (6) Corey, Larry < (b) (6) >;
 Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C] (b) (6) >;
 Doroshov, James (NIH/NCI) [E] < (b) (6) Goff, David (NIH/NHLBI) [E] < (b) (6) Heaton,
 Penny < (b) (6) King, James (b) (6) ; Kurilla, Mike (b) (6) ; Nayak,
 Seema (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) Payton, Manzine
 < (b) (6) Resnansky, Laura < (b) (6) Srinivasan, Badhri
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) Tountas, Karen (FNIH) [T]
 (b) (6) >; Vincent, Mike (b) (6) ; Wachtel, Jonathan (b) (6) ;
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bozzette,
 Sam (NIH/NCATS) [E] (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6)
 Butterson, Joan (b) (6) De Claro, R. Angelo (FDA/CDER) (b) (6)
 Draghia-Akli, Ruxandra < (b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith
 (b) (6) Hughes, Eric (b) (6) Judy, Currier
 < (b) (6) Kim, Elizabeth < (b) (6) LaVange, Lisa (b) (6) Levy, Elliot
 (b) (6) Mellors, John (b) (6) >; Menon, Sandeep < (b) (6) >; Parker,
 Ashley (NIH/OD) [E] (b) (6) ; Patel, Naimish < (b) (6) Peppercorn, Amanda
 (b) (6) >; Poole, Mike (b) (6) Proschan, Michael
 (b) (6) >; Read, Sarah (b) (6) Santos, Michael (FNIH) [T] (b) (6) ; Shen,
 Yuan Li (FDA/CDER) (b) (6) ; Stein, Peter (FDA/CDER) (b) (6) >; Adams, Peter
 (OS/ASPR/BARDA) (b) (6) ; Alvarez, Rosa (b) (6) >; Anderson, Annaliesa
 (b) (6) Baric, Ralph (b) (6) >; Carter, Kara (b) (6)
 Colvis, Christine <ccolvis@mail.nih.gov>; Deming, Damon (FDA/CDER) (b) (6) ; Diamond,
 Michael < (b) (6) Duncan, Ken < (b) (6) Fernandes, Prabhavathi
 (b) (6) >; Gatto, Greg (b) (6) ; Grobler, Jay < (b) (6) >; Hewitt, Judith
 < (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Lutz, Cat (b) (6)
 Menetski, Joseph (FNIH) [T] < (b) (6) Nestle, Frank (b) (6) Ottinger, Liz
 (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) Payne, David
 (b) (6) Rappaport, Jay (b) (6) ; Stegmeier, Frank < (b) (6)
 Young, John < (b) (6) Annunziato, Paula (b) (6) Arvin, Ann
 (b) (6) Buchbinder, Susan (b) (6) >; Corey, Larry < (b) (6)
 Davis, Mark < (b) (6) Emini, Emilio <emi (b) (6) Hanon, Emmanuel
 (b) (6) >; Haynes, Barton < (b) (6) Hotez, Peter (b) (6) >; Jansen,
 Kathrin (b) (6) ; Lanzavecchia, Antonio < (b) (6) Lowy, Douglas (NIH/NCI) [E]
 (b) (6) >; Marks, Peter (FDA/CBER) (b) (6) >; Mascola, John (NIH/VRC) [E]
 (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Offit, Paul
 (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) >; Santos, Nancy (b) (6) >;
 Schuitemaker, Hanneke (b) (6) Tartaglia, Jim (b) (6) >; Tolman, Brett
 (b) (6) (b) (6) (b) (6)

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:09 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Keith Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6) Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6)
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #19
Location: https://fnih.zoom. (b) (6)
Start: 5/20/2020 5:00:00 PM
End: 5/20/2020 6:00:00 PM

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/19/2020 2:32:20 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier
[redacted] (b) (6) Eric Hughes [redacted] (b) (6) LaVange, Lisa M [redacted] (b) (6)
Sandeep Menon [redacted] (b) (6) Proschan, Michael (NIH/NIAID) [E] [redacted] (b) (6) [redacted];
Read, Sarah (NIH/NIAID) [E] [redacted] (b) (6) [redacted]; Price, Dionne (FDA/CDER) [redacted] (b) (6) Rubin,
Daniel B. (FDA/CDER) [redacted] (b) (6) [redacted]; Farley, John (FDA/CDER) [redacted] (b) (6) Karen Lynn
Price [redacted] (b) (6) [redacted] (b) (6) [redacted] (b) (6) [redacted] (b) (6)
[redacted] (b) (6) [redacted] (b) (6) [redacted] (b) (6) Eron, Joe
[redacted] (b) (6) Javan, Arzhang (NIH/NIAID) [E] [redacted] (b) (6) Roa, Jhoanna [redacted] (b) (6)
[redacted] (b) (6) Kim, Peter (NIH/NIAID) [E] [redacted] (b) (6) Jonathan Li [redacted] (b) (6) Marks,
Gilbert (OS/ASPR/BARDA) (CTR) [redacted] (b) (6)
CC: Demarcus [redacted] (b) (6) Tountas, Karen (FNIH) [T] [redacted] (b) (6) [redacted]; Wachtel, Jonathan
[redacted] (b) (6) Elizabeth Kim [redacted] (b) (6) Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa
[redacted] (b) (6) Eron, Joseph J Jr [redacted] (b) (6) Smith, David
[redacted] (b) (6) Paul Klekotka [klekotka_pau [redacted] (b) (6) Ajay Nirula [redacted] (b) (6) Elsaid,
Olivia [redacted] (b) (6) Robert Jan Benschop [redacted] (b) (6) Lei Shen [redacted] (b) (6)
Subject: Confirmed: ACTIV TX-Clinical Neutralizing mAb Outpatient MP Writing Team Meeting
Attachments: ACTIV Therapeutics-Clinical mAb outpatient MP 19May2020 Agenda.pdf
Location: [https://fnih.zoom.us/j/\[redacted\] \(b\) \(6\)](https://fnih.zoom.us/j/[redacted] (b) (6))
Start: 5/19/2020 8:00:00 PM
End: 5/19/2020 9:30:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Judy Currier; Eric Hughes; Lisa LaVange; Sandeep Menon; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Farley, John (FDA/CDER); Karen Lynn Price; [redacted] (b) (6) [redacted] (b) (6) [redacted] (b) (6)
[redacted] (b) (6) [redacted] (b) (6) [redacted] (b) (6) Eron, Joe; Javan, Arzhang (NIH/NIAID) [E]; Roa, Jhoanna; [redacted] (b) (6) Kim, Peter (NIH/NIAID) [E]; Jonathan Li; Marks, Gilbert (OS/ASPR/BARDA) (CTR)
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Jhoanna Roa; Eron, Joseph J Jr; Smith, David; Paul Klekotka; Ajay Nirula; Elsaid, Olivia; Robert Jan Benschop; Lei Shen

Dear ACTIV-2 Writing Team,

This meeting is now confirmed. We should have quorum with people coming a little late or leaving a little early, but with the necessary overlap.

Please see the suggested attached agenda. Please let me know if you have additions or amendments.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 6/5/2020 3:45:03 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [Jacqueline.Kirchner@gatesfoundation.org]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [el (b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) ; Tolman, Brett [(b) (6) Alvarez, Rosa (b) (6)]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio (b) (6) Rose Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting #10
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200611_Final.pdf
Location: [https://fnih.zoom.us/j/\(b\) \(6\)](https://fnih.zoom.us/j/(b) (6))

Start: 6/11/2020 5:00:00 PM
End: 6/11/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
(NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;
Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman,
Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon;
Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy
(NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US;
Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]

Dear ACTIV Therapeutics-Clinical Working Group Members,

Please find attached the slides, which include the agenda for today's meeting.
We are looking forward to speaking with you all today.

In addition, just a reminder for those who might need it/be interested in sharing please find below the link to the agent survey to use for submission of an agent for consideration for prioritization.

Complete Survey Here: [ACTIV COVID-19 Clinical and Preclinical Candidate Compound Portal](#)

Thank again to all for your continued participation in this effort.

Best,
Stacey

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/15/2020 6:08:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups
Attachments: Master list for ACTIV 041520.xlsx

Francis – the following emails were missing from the list that went out, please see 8 emails listed below.

Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) >
Kim, Elizabeth < (b) (6) >
Marston, Hilary (NIH/NIAID) [E] < (b) (6) >
Paul, Steve < (b) (6) >
Payne, David < (b) (6) >
Plump, Andy < (b) (6) >
Santos, Nancy < (b) (6) >
Shen, Yuan Li (FDA/CDER) < (b) (6) >

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, April 15, 2020 11:39 AM
To: Melencio, Cheryl (FNIH) [T] < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

From: Melencio, Cheryl (FNIH) [T] < (b) (6) >
Sent: Wednesday, April 15, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >
Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bright, Rick < (b) (6) > Collins, Francis (NIH/OD) [E] < (b) (6) >; Corey, Larry < (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) >; Dolsten, Mikael < (b) (6) >; Erbelding, Emily (NIH/NIAID) [E] < (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Frankowski, David < (b) (6) >; Hudson, Thomas < (b) (6) >; James, Stephanie (FNIH) [T] < (b) (6) >; Klock, Kevin (FNIH) [T] < (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) >; Marks, Peter (FDA/CBER) < (b) (6) > Marston, Hilary (NIH/NIAID) [E] < (b) (6) >; Mascola, John < (b) (6) >; Meeker, David < (b) (6) >; Menetski, Joseph (FNIH) [T] < (b) (6) >; Pangalos, Mene < (b) (6) > Pao, William < (b) (6) > Paul, Steve < (b) (6) >; Perlmutter, Roger < (b) (6) > Plump, Andy < (b) (6) >; Rasi, Guido < (b) (6) >; Reed, John < (b) (6) >; Rouse,

Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel
 (b) (6) : Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) Tsai, John
 (b) (6) : Vessey, Rupert (b) (6) >; Virgin, Skip (b) (6) : Wholley, David
 (FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER) < (b) (6) >; Young, John
 < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) >; Bascles, Lionel
 (b) (6) Cohen, Myron < (b) (6) >; Corey, Larry (b) (6) ;
 Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C] (b) (6) >;
 Doroshow, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] < (b) (6) : Heaton,
 Penny < (b) (6) : King, James (b) (6) >; Kurilla, Mike < (b) (6) >; Nayak,
 Seema (NIH/NIAID) [E] (b) (6) : Parker, Ashley (NIH/OD) [E] < (b) (6) : Payton, Manzine
 (b) (6) >; Resnansky, Laura (b) (6) >; Srinivasan, Badhri
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) : Tountas, Karen (FNIH) [T]
 (b) (6) ; Vincent, Mike (b) (6) >; Wachtel, Jonathan (b) (6)
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) : Bozzette,
 Sam (NIH/NCATS) [E] < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6) >;
 Butterton, Joan (b) (6) >; De Claro, R. Angelo (FDA/CDER) (b) (6) >;
 Draghia-Akli, Ruxandra < (b) (6) : Eisner, Mark < (b) (6) : Gottesdiener, Keith
 (b) (6) >; Hughes, Eric (b) (6) >; Judy Currier
 < (b) (6) : Kim, Elizabeth (b) (6) ; LaVange, Lisa (b) (6) ; Levy, Elliot
 < (b) (6) : Mellors, John < (b) (6) : Menon, Sandeep < (b) (6) : Parker,
 Ashley (NIH/OD) [E] (b) (6) : Patel, Naimish (b) (6) >; Peppercorn, Amanda
 (b) (6) >; Poole, Mike < (b) (6) >; Proschan, Michael
 < (b) (6) ; Read, Sarah < (b) (6) : Santos, Michael (FNIH) [T] < (b) (6) : Shen,
 Yuan Li (FDA/CDER) (b) (6) : Stein, Peter (FDA/CDER) (b) (6) >; Adams, Peter
 (OS/ASPR/BARDA) (b) (6) >; Alvarez, Rosa < (b) (6) >; Anderson, Annaliesa
 (b) (6) : Baric, Ralph (b) (6) : Carter, Kara (b) (6) :
 Colvis, Christine (b) (6) : Deming, Damon (FDA/CDER) < (b) (6) : Diamond,
 Michael (b) (6) >; Duncan, Ken (b) (6) >; Fernandes, Prabhavathi
 (b) (6) >; Gatto, Greg (b) (6) : Grobler, Jay (b) (6) : Hewitt, Judith
 (b) (6) >; Jonson, Samantha (NIH/NCATS) [E] (b) (6) >; Lutz, Cat < (b) (6) :
 Menetski, Joseph (FNIH) [T] < (b) (6) : Nestle, Frank (b) (6) >; Ottinger, Liz
 (b) (6) : Parker, Ashley (NIH/OD) [E] (b) (6) : Payne, David
 < (b) (6) : Rappaport, Jay (b) (6) >; Stegmeier, Frank (b) (6) :
 Young, John < (b) (6) : Annunziato, Paula (b) (6) : Arvin, Ann
 (b) (6) : Buchbinder, Susan (b) (6) >; Corey, Larry < (b) (6) >;
 Davis, Mark < (b) (6) : Emini, Emilio < (b) (6) : Hanon, Emmanuel
 < (b) (6) : Haynes, Barton < (b) (6) : Hotez, Peter < (b) (6) : Jansen,
 Kathrin (b) (6) >; Lanzavecchia, Antonio < (b) (6) : Lowy, Douglas (NIH/NCI) [E]
 < (b) (6) : Marks, Peter (FDA/CDER) (b) (6) ; Mascola, John (NIH/VRC) [E]
 < (b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) ; Offit, Paul
 (b) (6) : Parker, Ashley (NIH/OD) [E] (b) (6) : Santos, Nancy (b) (6) >;
 Schuitemaker, Hanneke < (b) (6) : Tartaglia, Jim < (b) (6) : Tolman, Brett
 (b) (6) (b) (6) (b) (6)

Cheryl Melencio

Administrative Manager, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)

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APAR0000028956-2516881

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 12/10/2020 10:27:33 PM
To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6)
CC: (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,

Elizabeth [(b) (6)] btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6)] Diamond, Michael [(b) (6)] Rose Li [(b) (6)] Dana Carluccio [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6)] Dave Frankowski [(b) (6)] antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6)] Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; [(b) (6)] Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6)]

Subject: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us/> [(b) (6)]

Start: 12/18/2020 1:00:00 PM

End: 12/18/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; [(b) (6)] [(b) (6)] [(b) (6)]

[(b) (6)] [(b) (6)] [(b) (6)] [(b) (6)]
[(b) (6)] [(b) (6)] [(b) (6)] [(b) (6)]
[(b) (6)] [(b) (6)] [(b) (6)] [(b) (6)] Parker,
Ashley (NIH/OD) [E]; [(b) (6)]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu,
Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello
(NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; [(b) (6)]
[(b) (6)]

Optional Attendees: [(b) (6)] [(b) (6)] Wholley, David (FNIH) [T]; Austin, Christopher
(NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric;
Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen
(FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;
Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD)
[C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI)

[E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; (b) (6) .com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/j> (b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

(b) (6) US (Germantown)
US (Chicago)

Dial by your location

(b) (6) US (Germantown)
US (Chicago)
US (New York)
JS (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 3/4/2021 7:05:58 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Thanks for the update

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Thursday, March 4, 2021 1:38 PM
To: Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting

For updating our rosters, please see below.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Thursday, March 4, 2021 1:08 PM
To: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Thompson, Katherine (FNIH) [T] <(b) (6)>
Cc: Freire, Maria (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Gonzalez, Nina <(b) (6)>; Appell, Evan <(b) (6)>
Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting

Can we please add Gary Dubin to the Vaccine WG rosters on the NIH and FNIH websites, and substitute Rajeev Venkayya for Andy Plump as the rep for Takeda to the ACTIV Leadership Team?

Francis, I am assuming this means Andy is also asking that Rajeev replace him on the Executive Committee. He's got a good background for PPPs—worked for four years on the WH biodefense team (wherefrom he knows Tony Fauci), is Andy's counterpart at Takeda as global head of their vaccines business, directed vaccines delivery at BMGF, and serves on the boards of SEPI and IAVI. I found him engaging and impressive, and am guessing Mike did too.
Thanks, David

From: Burke, Leslie <(b) (6)> **On Behalf Of** Venkayya, Rajeev
Sent: Thursday, March 4, 2021 12:03 PM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>; Venkayya, Rajeev <(b) (6)>
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Mike,

I'm following up on Rajeev's behalf to let you know he would like to recommend his colleague **Gary Dubin, MD** (b) (6) for the Vaccines WG. Gary is the Head of our Global Medical Office, and leads the Takeda Vaccine Business Medical Affairs and Policy team. (b) (6) is his Executive Assistant.

Gary will look forward to connecting!

Please don't hesitate to reach out with any questions.

Many thanks,

Leslie Burke

EA to Rajeev Venkayya, MD, President, Global Vaccine Business Unit
Vaccine Business Unit

Takeda Pharmaceutical Company Limited

Mail to: 40 Landsdowne Street, Cambridge, MA 02139, USA

Office location: 75 Sidney Street, Cambridge, MA 02139, USA

mobile: (b) (6)

email: (b) (6) | www.takedavaccines.com

From: Santos, Michael (FNIH) [T] (b) (6)
Sent: Monday, March 1, 2021 12:04 PM
To: Venkayya, Rajeev (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] <(b) (6)>; Burke, Leslie (b) (6)
Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ: 社外から送信されたメールです

Hi Rajeev,

It was great meeting and chatting. Your experience and perspectives are a great addition to the group.

As we discussed, attached are notes from the last few Vaccines WG meetings. The meetings are not under NDA, but our principle is that information shared during the meetings should only be used to advanced the shared objective of supporting COVID-19 vaccine development. So please feel free to share with the relevant people in your team, but not publicly.

If anyone is interested in joining the Vaccines Working Group, please let us know and we'll be happy to add them.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Venkayya, Rajeev (b) (6)
Sent: Friday, February 19, 2021 11:21 PM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Wholley, David (FNIH) [T] (b) (6); Melencio, Cheryl (FNIH) [T] (b) (6); Burke, Leslie

(b) (6) >

Subject: Re: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Michael,

Thanks for the kind introduction and background. I know FNIH well and am looking forward to working with you. And yes, I'm sure we have many colleagues in common from BMGF!

An onboarding call would be helpful if it's not too much trouble. I'll ask Leslie to work with you to set that up. I look forward to that, and to meeting the ACTIV group!

Regards,

Rajeev

From: Santos, Michael (FNIH) [T] (b) (6) >

Sent: Friday, February 19, 2021 4:59:22 PM

To: Venkayya, Rajeev (b) (6) >

Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6)

Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Dear Rajeev,

We heard from Andy Plump and Francis Collins that you are joining ACTIV. We're delighted to have you on the team.

The Foundation for the NIH manages ACTIV; David Wholley leads our work overall, I manage the Vaccines Working Group, and my counterparts manage the other Working Groups. If you are interested, we would be happy to have a call to provide context on ACTIV and the Vaccines Working Group and answer any questions that you have.

On a personal note, I was at BMGF for almost 6 years on the Discovery and HIV teams before I joined FNIH in late 2019. Although we missed overlapping there, I'm sure we know many people in common and I hope that we'll have the opportunity to connect sometime.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Melencio, Cheryl (FNIH) [T] (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]

Sent: Friday, February 19, 2021 4:07 PM

To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Bancel, Stephane

(b) (6) >; Carter, Kara (b) (6) ; Cavaleri, Marco

(b) (6) >; Cihlar, Tomas (b) (6) ; Collins, Francis (NIH/OD) [E]

(b) (6) ; Corey, Larry <(b) (6)>; Culp, Michelle (NIH/OD) [E] (b) (6)

Victoria Davey (b) (6) ; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael

(b) (6) >; Embry, Alan (NIH/NIAID) [E] (b) (6) ; Erbeling, Emily (NIH/NIAID) [E]

APAR0000002192-2516883

(b) (6) Erck, Stan (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] < (b) (6)
 Freire, Maria (FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Gibbons, Gary
 (NIH/NHLBI) [E] (b) (6) >; Hudson, Thomas (b) (6) >; James, Stephanie (FNIH) [T]
 (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) (b) (6) >; Kramer, Lynn
 (b) (6) >; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John (b) (6) >;
 Marks, Peter (FDA/CBER) (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker,
 David (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) >; Messonnier, Nancy
 (CDC/DDID/NCIRD/OD) (b) (6) >; Pandya, Hitesh < (b) (6) >; Pangalos, Mene
 (b) (6) >; Pao, William (b) (6) >; Parker, Ashley (NIH/OD) [E]
 < (b) (6) >; Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6) >;
 Plenge, Robert < (b) (6) >; Reed, John (b) (6) >; Reese, David (b) (6) >;
 Rouse, Doris < (b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Skovronsky, Daniel
 (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Stoffels, Paul
 (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
 (b) (6) >; Tsai, John (b) (6) >; Venkayya, Rajeev < (b) (6) >;
 Vessey, Rupert (b) (6) >; Virgin, Skip (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >;
 Woodcock, Janet (FDA/OC) < (b) (6) >; Young, John (b) (6) >; Colvis,
 Christine (NIH/NCATS) [E] (b) (6) >; Desrosiers, Betsy (b) (6) >; Eric
 Hughes (b) (6) >; Jansen, Kathrin < (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) >; Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) >;
 Young, John (b) (6) >; Adam, Stacey (FNIH) [T] < (b) (6) >; Margaret Anderson
 (b) (6) >; Appell, Evan < (b) (6) >; Chen, Helen (b) (6) >;
 Connelly, Sarah (b) (6) >; Dally, Nicole (b) (6) >; Gonzalez, Nina
 < (b) (6) >; Hawk, Harrison < (b) (6) >; Mendelson, Jesse < (b) (6) >;
 Menetski, Joseph (FNIH) [T] (b) (6) >; Nasr, Hana (b) (6) >; Santos, Michael (FNIH) [T]
 (b) (6) >; Sorosa, Alex (b) (6) >; Stratton, Benjamin (b) (6) >; Tolman,
 Brett (b) (6) >; Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T]
 < (b) (6) >; Plump, Andrew (b) (6) >
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) >;
 Carluccio, Dana < (b) (6) >; Castillejos, Carlos < (b) (6) >; FNIH Central Account
 (b) (6) >; Lumsden, Joanne (NIH/NCATS) [C] (b) (6) >; Hallett, Adrienne
 (NIH/OD) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] < (b) (6) >; Myles, Renate (NIH/OD) [E]
 (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) >

Subject: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, February 17. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)
fnih.org
 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/29/2020 10:19:49 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Materials for July 29 ACTIV Executive Committee Teleconference
Attachments: 2020-07-01_ACTIV_Leadership_Team_Meeting_Summary FINAL.docx; 2020-07-15_Executive_Committee_Meeting_Summary vFinal.docx; 7.29 ACTIV Leadership Team Meeting 20200729 vFinal.pptx

FYI-LEADERSHIP TEAM SLIDES ATTACHED 7/29.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, July 28, 2020 10:53 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA)
<(b) (6)> Kramer, Lynn <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
<(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni
<(b) (6)> Rasi, Guido <(b) (6)> Reed, John <(b) (6)> Reese, David
<(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
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< (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6)

Subject: Materials for July 29 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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Sent: 7/29/2020 10:19:13 PM
Subject: FW: Materials for July 29 ACTIV Executive Committee Teleconference
Attachments: 2020-07-01_ACTIV_Leadership_Team_Meeting_Summary FINAL.docx; 2020-07-15_Executive_Committee_Meeting_Summary vFinal.docx; 7.29 ACTIV Leadership Team Meeting 20200729 vFinal.pptx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]

Sent: Tuesday, July 28, 2020 10:53 PM

To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane

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Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
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Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Anderson, James
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Foundation for the National Institutes of Health

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/18/2020 9:49:33 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6)]; Virgin,

Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) John Lepore [(b) (6) Grant, Sarah [(b) (6)

CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: ACTIV Leadership Team Meeting November 19, 2020
Attachments: 11.19 ACTIV Leadership Team Meeting 20201118_vF.pdf; 11.19 ACTIV Leadership Team Meeting
20201118_Appendix.pdf; 2020-10-21_ACTIV_Leadership_Team_Meeting_Summary-FINAL.docx; 2020-11-
04_Executive_Committee_Meeting_Summary_vF.pdf

Dear AMP Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Thursday, November 19 12:00 PM – 1:00 PM Eastern U.S. Time**. The minutes from the October 21 Leadership Team call as well as the minutes from the November 4 Executive Committee call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/14/2020 10:48:29 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]. (b) (6)
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Subject: ACTIV Preclinical working group (Friday meeting)

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: <https://fnih.zoom.us/> (b) (6)

Start: 4/24/2020 3:00:00 PM

End: 4/24/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Weekly
every Friday from 11:00 AM to 12:00 PM

Required Attendees: (b) (6) (b) (6) (b) (6) (b) (6)
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(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Louise Pitt (b) (6) Nancy Haigwood; Hild, Sheri (NIH/OD) [E]

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To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: DRAFT ACTIV Checkerboard_9.4.20.pdf

This might help. Or it might be too much info!

-----Original Message-----

From: Chen, Helen Q. <(b) (6)>
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)> ;
Butterton, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)>
Drachia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith
<(b) (6)> Eric Hughes <(b) (6)> ; Judy Currier
<(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)>
Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish
<(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
(NIH/NIAID) [E] <reads@niaid.nih.gov>; Santos, Michael (FNIH) [T] <msantos@tnih.org>; Shen, Yuan Li
(FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Wholley, David
(FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva
(FDA/CDER) <(b) (6)> Amanda Peppercorn <amanda.(b) (6)> Garner, Carl
<(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter
(NIH/NINDS) [E] <(b) (6)> Timothy Burgess <(b) (6)> Reineck, Lora
(NIH/NHLBI) [E] <(b) (6)> Adairwal, Neil (NIH/NHLBI) [E] <(b) (6)>
Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E]
<(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Jacqueline Kirchner
<(b) (6)> Beigel, John (NIH) [E] <(b) (6)> Phillips, L
Revell CIV DTRA RD (USA) <(b) (6)> Petrovick, Martha - 0449 - MITLL
<(b) (6)> Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael
(NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John
<(b) (6)> Briggs, Mary <(b) (6)> Butcher, Tina <(b) (6)> ;
Demarcus <(b) (6)> Macone, Erin <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Salathin, Carla <(b) (6)> Tountas, Karen (FNIH) [T]
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Wachtel, Jonathan <(b) (6)> Stolman <(b) (6)> Alvarez,
Rosa Maria <(b) (6)> Gonzalez, Nina <(b) (6)> Dana Carluccio
<(b) (6)> Rose Li Central Account <(b) (6)> Margaret
Anderson <(b) (6)> Lucas Smalldon <(b) (6)> Stratton,
Benjamin <(b) (6)> Mollica, Linda /US
<(b) (6)> Oashu, Felicia (NIH/OD) [E] <(b) (6)> Patterson, Amy
(NIH/NHLBI) [E] <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Marston,
Hilary (NIH/NIAID) [E] <(b) (6)> Wung, Peter /US <(b) (6)> Hoots, W. Keith
(NIH/NHLBI) [E] <(b) (6)> Groesch, Mary (NIH/NHLBI) [E] <(b) (6)> Shipp,
Allan (NIH/NHLBI) [E] <(b) (6)> Kindzelski, Andrei (NIH/NHLBI) [E]
<(b) (6)> Hone, David M (Dave) CIV DTRA J9 (USA) <(b) (6)>
Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) <(b) (6)> Freire, Maria (FNIH)
[T] <(b) (6)> Elsaid, Olivia <(b) (6)> Appell, Evan <(b) (6)>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; rwmalonemd@gmail.com; Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;
(b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/> (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
<https://fnih.zoom.us/>; (b) (6)

Meeting ID: (b) (6)
Password: (b) (6)
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(b) (6) US (Germantown)
US (Chicago)

Dial by your location
(b) (6) US (Germantown)
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US (New York)
US (Tacoma)
US (Houston)
US (San Jose)
US (San Jose)

Meeting ID: (b) (6)
Password: (b) (6)
Find your local number: <https://fnih.zoom.us/j/9461354567> This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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GADB0000000604-2516889

From: (b) (6) [(b) (6)]
Sent: 5/13/2020 10:46:47 AM
To: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]
Subject: Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leadership-vF 051220.pdf; ATT00002.htm

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" (b) (6)
Date: May 12, 2020 at 9:57:04 PM EDT
To: "Collins, Francis (NIH/OD) [E]" (b) (6), "Dolsten, Mikael" (b) (6), "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) >, "Gibbons, Gary (NIH/NHLBI) [E]" (b) (6), >, "Pao, William" < (b) (6) >, "Stoffels, Paul [JJCUS]" < (b) (6) >, "Woodcock, Janet (FDA/CDER)" < (b) (6) >, "Colvis, Christine (NIH/NCATS) [E]" (b) (6), >, "Desrosiers, Betsy" (b) (6), "Hughes, Eric" (b) (6), "Jansen, Kathrin" (b) (6), "Kurilla, Michael (NIH/NCATS) [E]" (b) (6), >, "Lowy, Douglas (NIH/NCI) [E]" (b) (6), "Read, Sarah (NIH/NIAID) [E]" (b) (6), "Young, John" (b) (6), >, "Menetski, Joseph (FNIH) [T]" (b) (6), "Adam, Stacey (FNIH) [T]" (b) (6), "Tountas, Karen (FNIH) [T]" (b) (6), "Santos, Michael (FNIH) [T]" (b) (6), "Freire, Maria (FNIH) [T]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Lane, Cliff (NIH/NIAID) [E]" (b) (6), "Parker, Ashley (NIH/OD) [E]" (b) (6), "Anderson, James (NIH/OD) [E]" < (b) (6) >, "Austin, Christopher (NIH/NCATS) [E]" (b) (6), >, "Wolf-Rodda, Julie (FNIH) [T]" (b) (6), >, "Gonzalez, Nina" < (b) (6) >
Cc: "Melencio, Cheryl (FNIH) [T]" (b) (6), >, "Wood, Gretchen (NIH/OD) [E]" < (b) (6) >
Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:
Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

APAR0000028905-2516890

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Sizemore, Christine (NIH/FIC) [E] [(b) (6)]; Beigel, John (NIH) [E] [(b) (6)] Culp, Michelle (NIH/OD) [E] [(b) (6)] Brown, Jeremy (NIH/NINDS) [E] [(b) (6)] Goff, David (NIH/NHLBI) [E] [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)] Reineck, Lora (NIH/NHLBI) [E] [(b) (6)] Timothy Burgess [(b) (6)] Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)].gov]; Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)] Collins, Sylva (FDA/CDER) [(b) (6)] Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)] Wholley, David (FNIH) [T] [(b) (6)] Stein, Peter (FDA/CDER) [(b) (6)]; Shen, Yuan Li (FDA/CDER) [(b) (6)] Santos, Michael (FNIH) [T] [(b) (6)] Read, Sarah (NIH/NIAID) [E] [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [(b) (6)] Parker, Ashley (NIH/OD) [E] [(b) (6)] Mellors, John W [(b) (6)] Judy Currier [(b) (6)] Eric Hughes [(b) (6)] De Claro, R. Angelo (FDA/CDER) [(b) (6)] Butterson, Joan [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Levy, Elliot [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) com]; Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn [(b) (6)] Garner, Carl [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves

(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV
DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai
[(b) (6) Wung, Peter K [(b) (6)
CC: Embry, Alan (NIH/NIAID) [E] (b) (6) Lerner, Andrea (NIH/NIAID) [E] [(b) (6)
Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)]; Sorosa, Alex David [(b) (6) Walker,
Paula (NIH/NINDS) [E] [(b) (6) Kindzelski, Andrei (NIH/NHLBI) [E] [(b) (6)];
Shipp, Allan (NIH/NHLBI) [E] [allan. (b) (6) Groesch, Mary (NIH/NHLBI) [E] [(b) (6)]; Hoots,
W. Keith (NIH/NHLBI) [E] [(b) (6) .gov]; Chen, Helen Q. [(b) (6) Marston, Hilary
(NIH/NIAID) [E] [(b) (6) Rubin, Daniel B. (FDA/CDER) [(b) (6) Patterson, Amy
(NIH/NHLBI) [E] [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Menetski, Joseph
(FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Lowy, Douglas (NCI)
[(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
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[(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio
[(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
[(b) (6) Mollica, Linda /US
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W. Keith
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerpl]; Sorosa, Alex

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Attachments: ACTIV_TX-Clinical WG Meeting_20210225_v1.pdf

Start: 2/25/2021 6:00:00 PM
End: 2/25/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Levy, Elliot; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. See you in a few minutes.

Thanks,
Stacey

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
 (b) (6) : (b) (6) (b) (6) (b) (6) (b) (6)
 Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
 (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
 Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6)]
 Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)]
 Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp];
 (b) (6) (b) (6) (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]
 Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)]
 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6)]
 Kim, Elizabeth [(b) (6)] Tolman, Brett [(b) (6)] Wachtel, Jonathan [(b) (6)]
 Prabhavathi Fernandes [(b) (6)] Rose Li [(b) (6)]
 Dana Carluccio [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Diamond, Michael
[(b) (6)

Start: 7/1/2020 2:00:00 PM
End: 7/1/2020 3:00:00 PM

Recurrence: (none)

From: Connelly, Sarah [(b) (6)]
Sent: 12/1/2020 10:12:01 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6)
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CC: Diamond, Michael [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [rose.l (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen (b) (6) (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
Preclinical WG Strategic Objectives - Updates	20 mins	Joe Menetski John Young Christine Colvis
Discuss Viral Mutation and Prediction of Escape	20 mins	Joe Menetski John Young Christine Colvis
Discuss Subgroup updates <ul style="list-style-type: none"> ○ Preclinical prioritization ○ In vivo strategy <ul style="list-style-type: none"> ○ Field Guides ○ Viral Stocks ○ Data portal implementation 	10 mins	John Young Nancy Haigwood Cat Lutz Isis Kanevsky Clint Florence Sam Jonson
Discuss Small Animal Models and NHP Field Guides	10 mins	Nancy Haigwood Cat Lutz Isis Kanevsky

Looking forward to talking to everyone tomorrow!

All the best,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP

Tel/Direct: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Tuesday, April 14, 2020 6:43 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)

(b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6); Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Diamond, Michael; Mason, Stephen;

(b) (6); Connelly, Sarah

Subject: ACTIV Preclinical full working group

When: Wednesday, November 11, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us> (b) (6)

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From: Mellors, John W [(b) (6)]
Sent: 10/29/2020 5:29:50 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Amanda Peppercorn [(b) (6)]; Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV
DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
(b) (6)

CC: Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
[(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio
[(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon
[(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US
[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e];
Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk];
Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
[(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd];
Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes
[(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] [mailto: (b) (6)]
Sent: Wednesday, June 17, 2020 8:47 AM
To: Adam, Stacey (FNIH) [T]; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschian, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revelle CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)
Cc: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio: Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6)
Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; asorosa
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, October 29, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> (b) (6)

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting in 20 minutes.

Thanks,
Stacey

Join Zoom Meeting

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(b) (6)

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From: Alvarez, Rosa Maria [(b) (6)]
Sent: 8/10/2020 3:01:56 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6); (b) (6); (b) (6); (b) (6)
(b) (6); (b) (6); (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li

[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020-08-05_Preclinical_WG_Summary_RLA_vF.docx

Hi all,

Hope you had a good weekend. Please see attached for the notes from our last WG meeting on 8/5. Please let us know if you suggest any modifications or have any questions.

Best regards,
Rosa

Rosa M. Álvarez
Deloitte Consulting LLP
Mobile: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6); (b) (6);

(b) (6); (b) (6); (b) (6); (b) (6);
(b) (6); (b) (6); Baric, Ralph; (b) (6); Ottinger, Elizabeth (NIH/NCATS
[E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E]; Collins, Francis
(NIH/OD) [E]; (b) (6); Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)
[E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy;
Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E];
Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa
Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C];

Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Wednesday, August 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>. (b) (6)

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 6/11/2020 7:38:52 PM
To: Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li

(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us> (b) (6)

Start: 7/29/2020 2:00:00 PM

End: 7/29/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) .gov;
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6); Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Optional Attendees: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E];
Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam,
Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel,
Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
(NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood;
Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/21/2020 4:54:26 PM
To: Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea];
[(b) (6)] [(b) (6)] [(b) (6)] Adams, Peter
(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Pitt, Margaret L CIV
USARMY MEDCOM USAMRIID (USA) [(b) (6)] [(b) (6)]
[(b) (6)] [(b) (6)] [(b) (6)] [(b) (6)]
[(b) (6)] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
[(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
[(b) (6)] [(b) (6)] [(b) (6)] Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rao, Srinivas
[(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar
[(b) (6)]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Wholley, David (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6)] Hughes, Eric [(b) (6)] Jansen, Kathrin
[(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
[(b) (6)] Kim, Elizabeth [(b) (6)] Tolman, Brett [(b) (6)] Wachtel,
Jonathan [(b) (6)] Prabhavathi Fernandes [(b) (6)] Diamond, Michael
[(b) (6)] Rose Li [(b) (6)] Dana Carluccio
[(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical working group (Tuesday meeting)

Attachments: 2020-05-20_Preclinical_WG_Summary_F1.docx

Dear Preclinical Working group members and attendees,

Please find the minutes from yesterday's meeting attached. Thank you for a very interesting meeting and all of the work you continue to do for the ACTIV effort.

Best regards,

Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) (b) (6) (b) (6)
Adams, Peter (OS/ASPR/BARDA); Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Menetski, Joseph (FNIH) [T];
(b) (6) (b) (6) (b) (6) (b) (6)
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(b) (6) (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar
Cc: Simon, Dina (NIH/OD) [C]; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, May 20, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

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From: (b) (6) [(b) (6)]
Sent: 5/29/2020 10:44:42 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] < (b) (6) > wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] < (b) (6) >
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gonzalez, Nina < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to

highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) - in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2*– Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS “Master” Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
 - * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)

- All three companies have written their sections of the protocols, which are being merged into the master design
 - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
 Senior Vice-President, Research Partnerships
 Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

From: (b) (6) [(b) (6)]
Sent: 2/13/2021 4:55:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Barasch, Kimberly (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; (b) (6)
[(b) (6) (b) (6) [(b) (6) (b) (6)]
[(b) (6) (b) (6) (b) (6) (b) (6)]
[(b) (6) (b) (6) [(b) (6)]
Subject: Re: [EXTERNAL] a few follow ups

Francis
Thanks for generously suggesting Monday.
I can make myself available also.

Gretchen and Ann can explore if we can get our dream team cross NIH/Pfizer together that day

Best
(b) (6)

On Feb 13, 2021, at 11:49 AM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Though it's a federal holiday, Monday might also be a possibility – I'd be fine with that.

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, February 13, 2021 11:17 AM
To: (b) (6) (b) (6)
Cc: Fauci, Anthony (NIH/NIAID) [E] < (b) (6) > Lane, Cliff (NIH/NIAID) [E]
< (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Wood, Gretchen (NIH/OD) [E]
< (b) (6) > Barasch, Kimberly (NIH/NIAID) [E] < (b) (6) > Conrad, Patricia

(NIH/NIAID) [E] < (b) (6)

Subject: RE: [EXTERNAL] a few follow ups

Hi Mikael,

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

From: (b) (6) (b) (6)

Sent: Friday, February 12, 2021 2:32 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group, I am pleased also to present the protease drug highlights myself and John together with our CEO Albert Bourla from Pfizer to meet the three of you

Best
(b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16, (b) (6) wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team. We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you, Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Coronavirus protease inhibitor (PI) drugs.

In this time of SARS-CoV2 viral evolution, they seem like a drug class with great promise.

We have submitted the IV PI drug to ACTIV with positive reception. We are planning to submit the oral PI drug to ACTIV on Wednesday next week.

Albert will join me in the meeting with you. If you want to have some more detailed background science on the drugs, I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton. Liesa participated in ACTIV since the start within therapeutics related work streams.

COLL0000012362-2516899

Look forward to your response

Best
(b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E]

(b) (6) > wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? 😊 I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

From: (b) (6) >
Sent: Wednesday, February 10, 2021 8:36 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article but TIME paper was great

The exciting piece w the antiviral protease inhibitor (PI) drugs is that they are pan-corona virus active w potential as a drug for any new pandemic coronavirus. They also will inhibit all presently known SARS-CoV2 mutant variants that mainly affect SPIKE

Confidential update

(b) (4)

(b) (4)

(b) (6)

Sent from my iPhone

On Feb 10, 2021, at 06:33, Collins, Francis (NIH/OD) [E]

(b) (6) > wrote:

Hi (b) (6)

Just checking in. First, thanks for your kind words that were quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 10/11/2020 2:44:29 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Roster of ACTIV Vaccines WG

Mike, thank you very much for handling this. Francis, I trust you have what you need?

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Saturday, October 10, 2020 5:34 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

In case you were looking for the opposite of what I sent in my previous email, this is the list of WG members who are also on the Clinical Trials Sub-Group.

Thanks,
Mike

Name	Organization
Paula Annunziato	Merck
Larry Corey	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Emilio Emini	Gates
Gregory M. Glenn	Novavax
Marion Gruber	CBER/FDA
Peter Hotez	Baylor and Texas Children's
Kathrin Jansen	Pfizer
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Paul Offit	Penn/CHOP
Tal Zaks	Moderna

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Saturday, October 10, 2020 3:10 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] (b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, no problem. The list below is only the non-WG members of the Sub-Group.

Thanks,

Mike

Name	Organization
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douoguih	J&J
Peter Dull	Gates
Emily Erbeling	NIAID/NIH
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK
Bill Gruber	Pfizer
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Laurent Humeau	Inovio
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH

Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Saturday, October 10, 2020 2:31 PM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6); Freire, Maria (FNIH) [T] (b) (6)
Subject: Re: Roster of ACTIV Vaccines WG

Can you do me a favor and just pull out the names and institutions of the people who are not on the Vaccines WG?

Sent from my iPhone

On Oct 10, 2020, at 2:21 PM, Santos, Michael (FNIH) [T] (b) (6) > wrote:

Hi Francis,

We don't maintain as nice of a version of the Sub-Group rosters, but here is the Clinical Trials Sub-Group list of names and organizations (some of which overlap with the main WG). We also commonly have additional guests depending on the topic, so if there's an organization or expertise that you're looking for that is not represented, we can invite them to a meeting ad hoc.

Thanks,
Mike

Name	Organization
Paula Annunziato (co-chair)	Merck
Larry Corey (co-chair)	Fred Hutch
Ann Arvin	Stanford
Beth Bell	UW
Marco Cavaleri	EMA
Myron Cohen	UNC
Elizabeth Desrosiers	Merck
Macaya Douoguih	J&J
Peter Dull	Gates
Emilio Emini	Gates
Emily Erbeling	NIAID/NIH
Gregory M. Glenn	Novavax
Peter Gilbert	SCHARP/UW
Paul Gillard	GSK

Bill Gruber	Pfizer
Marion Gruber	CBER/FDA
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Peter Hotez	Baylor and Texas Children's
Laurent Humeau	Inovio
Kathrin Jansen	Pfizer
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	J&J
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Paul Offit	Penn/CHOP
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	J&J
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna
Tal Zaks	Moderna

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)

Sent: Saturday, October 10, 2020 12:47 PM

To: Santos, Michael (FNIH) [T] <[REDACTED]> (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> (b) (6); Wholley, David (FNIH) [T] <[REDACTED]> (b) (6)

Freire, Maria (FNIH) [T] <[REDACTED]> (b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

COLL0000013778-2516900

Thanks, this is helpful. Have you got a roster of the Clinical Trials Sub-Group?

From: Santos, Michael (FNIH) [T] <m (b) (6)>
Sent: Saturday, October 10, 2020 11:47 AM
To: Collins, Francis (NIH/OD) [E] (b) (6) >
Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Wholley, David (FNIH) [T] (b) (6)
Freire, Maria (FNIH) [T] (b) (6)
Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, I'd be happy to convene a meeting of the WG.

The WG membership is attached. We also have a wider group of people that have been part of the sub-groups, so depending on the topic and the ask we could invite them as well (e.g., for a clinical trials question we could convene the WG plus the Clinical Trials Sub-Group).

For next steps, if we can know a little more about the topic and the desired timing, I'm happy to connect with Kathrin and Doug and schedule a meeting with the appropriate set of people.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, October 10, 2020 11:33 AM
To: Santos, Michael (FNIH) [T] (b) (6)
Cc: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Wholley, David (FNIH) [T] (b) (6)
Freire, Maria (FNIH) [T] (b) (6)
Subject: Roster of ACTIV Vaccines WG

Hi Mike,

We might need to reconvene the ACTIV Vaccines WG for some advice about management of next steps for the trials. Can you send me the roster?

Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/1/2020 4:09:11 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Confirm Attendance: July 1 ACTIV Leadership Call #5
Flag: Follow up

From: David Meeker <(b) (6)>
Sent: Wednesday, July 1, 2020 9:11 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: Re: Confirm Attendance: July 1 ACTIV Leadership Call #5

Apologies David. I will attend. Best. David

Sent from my iPhone

On Jul 1, 2020, at 9:09 AM, Wholley, David (FNIH) [T] (b) (6) wrote:

WARNING: This email originated from outside of KSQ. Proceed with caution.

Dear David - Will you be on today's call, and can you please confirm back to Cheryl and me? Thanks,
David Wholley

From: Melencio, Cheryl (FNIH) [T] (b) (6) >
Sent: Monday, June 29, 2020 1:18 PM
To: Cavaleri, Marco <(b) (6)> Cihlar, Tomas (b) (6) >;
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Erbelding, Emily (NIH/NIAID) [E]
(b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> >; Johnson, Robert
(OS/ASPR/BARDA) <(b) (6)> ; Lee, William (b) (6) ; Lepore, John
(b) (6) ; Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker, David
(b) (6) ; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6)
(b) (6) ; Plenge, Robert (b) (6) ; Reed, John (b) (6) >;
Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6)
Talley, Michael (b) (6) ; Vessey, Rupert (b) (6) ; Woodcock, Janet
(FDA/CDER) (b) (6) ; Jansen, Kathrin (b) (6) >
Cc: Giorgi, Sara (b) (6) >; Dimishkov, Roxanne (NIH/NHLBI) [C]
(b) (6) ; MacDougall, Cheryl (b) (6) ; Thomas, Ashley
(FDA/CDER) (b) (6)
Subject: Confirm Attendance: July 1 ACTIV Leadership Call #5

Good afternoon,

Please confirm your attendance for the ACTIV Leadership Call on Wednesday, July 1 – 1-2:30 p.m. Eastern time.

Thank you for your assistance.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image001.png>

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/18/2020 1:58:04 PM
To: (b) (6)
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, May 16, 2020 6:02 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Myles, Renate (NIH/OD) [E] - (b) (6); Meltzer, Abbey (FNIH) [T] (b) (6); Wholley, David (FNIH) [T] (b) (6) >
Subject: URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/18/2020 2:27:15 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public
Flag: Follow up

Should we just include her? I need to push the website live.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 18, 2020 9:58 AM
To: (b) (6)
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>
Subject: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Saturday, May 16, 2020 6:02 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>
Subject: URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

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Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/1/2020 12:47:20 PM
To: Srinivasan, Badhri [(b) (6)] Vincent, Mike [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.King.]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Wachtel, Jonathan [(b) (6)] Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Garner, Carlos [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Carluccio, Dana [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6)] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Minnich, Beth [(b) (6)] Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05012020.pdf; Innovations Matrix 1May2020.xlsx
Location: https://zoom. (b) (6)
Start: 5/1/2020 1:00:00 PM
End: 5/1/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Srinivasan, Badhri; Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzone; Resnansky, Laura; Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Attaching the most recent version of the innovations matrix. Karen

Dear Colleagues, Agenda is attached. During this call we will hear the latest from the three sub-WGs – innovations, inventory, and survey – which have been working very hard to move their activities forward quickly. Many thanks to all! We will also have a bit of a brainstorming session about creating a ‘dashboard’ to use in analyzing survey results. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,


In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/18/2020 2:28:44 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: FW: ACTIV Executive Committee Meeting 202005017dw.pptx
Attachments: ACTIV Executive Committee Meeting 202005018.pptx

For our meeting in three minutes sorry for the late send.

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 7/20/2020 6:42:35 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: did you get an invite for the July 15 Exec Comm meeting?

Hi Michelle,

It dawned on me too late that I didn't have the July 15 ACTIV Executive Committee Teleconference on my calendar. I got the slides from David in the email below, but I don't think I ever got the invitation. Did you get the invitation? I shouldn't miss the next one.

Thanks,
Ellen

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, July 14, 2020 8:44 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William <(b) (6)>
Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)>
Desrosiers, Betsy <(b) (6)> Eric Hughes <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>
Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Burklow, John (NIH/OD) [E] <(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
FNIH Central Account <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)>
Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)>
Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)> Chen, Helen <(b) (6)> Elsaid, Olivia <(b) (6)> Gonzalez, Nina <(b) (6)>
James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Stratton, Ben <(b) (6)> Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)>
Wholley, David (FNIH) [T] <(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)>
Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: Materials for July 15 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 PM to 4:30 PM Eastern U.S. time tomorrow, Wednesday July 15. I have also attached notes from our July 1 Leadership Team meeting as well as our last EC meeting on June 17.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Mellors, John W (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Proshan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Jacqueline Kirchner [(b) (6) Garner, Carl [(b) (6) Menon, Sandeep [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier

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 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
 Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6)
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[(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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[carla. (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Dana
Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret
Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Stratton, Benjamin [(b) (6)
(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US
[(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) [(b) (6) (b) (6) USARMY DOD JPEO CBRND (USA)
(b) (6)

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200723.pdf

Start: 7/23/2020 5:00:00 PM
End: 7/23/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Jacqueline Kirchner; Garner, Carl; Menon, Sandeep; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; (b) (6) DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; (b) (6) CIV DTRA J9 (USA); (b) (6) USARMY DOD JPEO CBRND (USA)

Dear ACTIV TX-Clinical WG members,

Please find attached the slides for today's meeting with the agenda.
We will have a speaker from NIAID presenting on a new master protocol idea.

Thanks,
Stacey

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To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) Baric, Ralph
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria (b) (6) Kim, Elizabeth (b) (6) btolman (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina (b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen [Stephen. (b) (6) Connelly, Sarah [(b) (6) (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd [(b) (6) (b) (6) Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; (b) (6) Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Diamond, Michael [(b) (6)

Start: 2/17/2021 3:00:00 PM
End: 2/17/2021 4:00:00 PM

Recurrence: (none)

From: Harris, Kathryn (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=79D72A4A3DCB43E785C83411756CD9E7-HARRISKATH]
Sent: 12/18/2020 8:34:31 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0ff5e52c31a4-tuckerjm]; O'Reilly, Marina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d6c68e99e94ea6bc7872cfbf0d0176-oreillym]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: ACTIV slides from today on escape mutations

Well BARDA making grantees follow GLs (based on the vaccine stuff they had come to us)

From: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Sent: Friday, December 18, 2020 3:32 PM
To: O'Reilly, Marina (NIH/OD) [E] <(b) (6)> Harris, Kathryn (NIH/OD) [C] <(b) (6)>
Cc: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Subject: FW: ACTIV slides from today on escape mutations

More from Ellen on this.

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Friday, December 18, 2020 12:11 PM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

And more from the FNIH/Deloitte call—Moncef Slaoui is going to ask BARDA for the funds for this project. FNIH is prepping a budget.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Friday, December 18, 2020 10:41 AM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

More today on the ACTIV preclinical WG call: FYI this whole effort also includes escape mutants from the vaccines, not just the therapeutics. And I think the member from Roche said something like there are already mutations known to affect efficacy of cocktails (presumably of antibodies), but I am not sure I heard that right. At any rate, I keep hearing the FDA is requiring companies to generate this information.

From: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, December 16, 2020 4:17 PM
To: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV slides from today on escape mutations

Thank you!

From: Gadbois, Ellen (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, December 16, 2020 1:16 PM
To: Tucker, Jessica (NIH/OD) [E] <(b) (6)>
Subject: FYI: ACTIV slides from today on escape mutations

See slides 6-10. Note that slide 8 includes "selection screens." There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
 Bancel, Stephane <(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
 <(b) (6)> Cihlar, Tomas <(b) (6)> >; Collins, Francis (NIH/OD) [E]
 <(b) (6)> >; Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
 Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
 <(b) (6)> ; Erbelding, Emily (NIH/NIAID) [E] <(b) (6)> >; Erck, Stan
 <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> >; Freire, Maria (FNIH) [T]
 <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E]
 <(b) (6)> >; Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
 <(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
 <(b) (6)> ; Lane, Cliff (NIH/NIAID) [E] <(b) (6)> >; Lepore, John <(b) (6)>
 Marks, Peter (FDA/CBER) <(b) (6)> >; Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
 Mascola, John (NIH/VRC) [E] <(b) (6)> >; Meeker, David <(b) (6)> Menetski, Joseph
 (FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
 <(b) (6)> >; Pangalos, Mene <(b) (6)> >; Pao, William
 <(b) (6)> >; Parker, Ashley (NIH/OD) [E] <(b) (6)> >; Paul, Steve <(b) (6)>
 Perlmutter, Roger <(b) (6)> >; Plenge, Robert <(b) (6)> >; Plump, Andy
 <(b) (6)> >; Rachel Ramoni <(b) (6)> Reed, John <(b) (6)> Reese,
 David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
 Skovronsky, Daniel <(b) (6)> ; Stein, Peter (FDA/CDER) <(b) (6)> >; Stoffels, Paul
 <(b) (6)> >; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Talley, Michael
 <(b) (6)> >; Tsai, John <(b) (6)> >; Vessey, Rupert <(b) (6)> Virgin, Skip
 <(b) (6)> ; Woodcock, Janet (FDA/CDER) <(b) (6)> ; Young, John
 <(b) (6)> >; Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
 <(b) (6)> ; Eric Hughes <(b) (6)> ; Jansen, Kathrin
 <(b) (6)> ; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> ; Lowy, Douglas (NCI)
 <(b) (6)> ; Read, Sarah (NIH/NIAID) [E] <(b) (6)> ; Young, John <(b) (6)>
 Adam, Stacey (FNIH) [T] <(b) (6)> ; Margaret Anderson <(b) (6)> ; Appell, Evan
 <(b) (6)> ; Chen, Helen Q. <(b) (6)> >; Connelly, Sarah <(b) (6)>
 Gonzalez, Nina <(b) (6)> ; Hawk, Harrison <(b) (6)> ; Mendelson, Jesse
 <(b) (6)> ; Menetski, Joseph (FNIH) [T] <(b) (6)> ; Nasr, Hana <(b) (6)>
 Santos, Michael (FNIH) [T] <(b) (6)> ; Sorosa, Alex David <(b) (6)> >; Stratton, Benjamin
 <(b) (6)> ; btolman <(b) (6)> ; Tountas, Karen (FNIH) [T] <(b) (6)>
 Wachtel, Jonathan <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> >; Austin, Christopher (NIH/NCATS) [E]
 <(b) (6)> ; Burklow, John (NIH/OD) [E] <(b) (6)> ; Carluccio, Dana
 <(b) (6)> ; Castillejos, Carlos <(b) (6)> ; FNIH Central Account
 <(b) (6)> ; Hallett, Adrienne (NIH/OD) [E] <(b) (6)> >; Lane, Cliff (NIH/NIAID) [E]
 <(b) (6)> ; Myles, Renate (NIH/OD) [E] <(b) (6)> ; Parker, Ashley (NIH/OD) [E]
 <(b) (6)> ; Tabak, Lawrence (NIH/OD) [E] <(b) (6)> ; Wolinetz, Carrie (NIH/OD) [E]
 <(b) (6)> ; Meltzer, Abbey (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]

Sent: Tuesday, December 15, 2020 5:08 PM

To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane

(b) (6) >; Carter, Kara <(b) (6)> >; Cavaleri, Marco

(b) (6) Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E]

<coll (b) (6) Corey, Larry <(b) (6) Culp, Michelle (NIH/OD) [E] <(b) (6)

Victoria Davey (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) Dolsten, Mikael

(b) (6) >; Erbelding, Emily (NIH/NIAID) [E] (Erck, Stan

(Fauci, Anthony (NIH/NIAID) [E] (b) (6) Freire, Maria (FNIH) [T]

(b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Gibbons, Gary (NIH/NHLBI) [E]

(b) (6) Hudson, Thomas (b) (6) >; James, Stephanie (FNIH) [T]

(b) (6) Johnson, Robert (OS/ASPR/BARDA) <(b) (6) Kramer, Lynn

(b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John <(b) (6)

Marks, Peter (FDA/CBER) (b) (6) >; Marston, Hilary (NIH/NIAID) [E] (b) (6) >;

Mascola, John (NIH/VRC) [E] (b) (6) Meeker, David (b) (6) Menetski, Joseph

(FNIH) [T] (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) >; Pandya, Hitesh

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(b) (6) Parker, Ashley (NIH/OD) [E] <(b) (6) >; Paul, Steve (b) (6)

Perlmutter, Roger (b) (6) Plenge, Robert <(b) (6) Plump, Andy

(b) (6) >; Rachel Ramoni (b) (6) >; Reed, John (b) (6) >; Reese,

David <(b) (6) Rouse, Doris (b) (6) Santos, Michael (FNIH) [T] (b) (6) >;

Skovronsky, Daniel (b) (6) Stein, Peter (FDA/CDER) (b) (6) Stoffels, Paul

(b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael

(b) (6) Tsai, John (b) (6) Vessey, Rupert (b) (6) >; Virgin, Skip

(b) (6) Wholley, David (FNIH) [T] <(b) (6) Woodcock, Janet (FDA/CDER)

<(b) (6) Young, John <(b) (6) Colvis, Christine (NIH/NCATS) [E]

(b) (6) >; Desrosiers, Betsy (b) (6) Eric Hughes

(b) (6) >; Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E]

(b) (6) Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6)

Young, John (b) (6) Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson

(b) (6) >; Appell, Evan (b) (6) >; Chen, Helen Q. (b) (6)

Connelly, Sarah (b) (6) >; Gonzalez, Nina (b) (6) Hawk, Harrison

(b) (6) Mendelson, Jesse (b) (6) >; Menetski, Joseph (FNIH) [T]

< (b) (6) Nasr, Hana (b) (6) Santos, Michael (FNIH) [T] (b) (6) Sorosa,
Alex David < (b) (6) >; Stratton, Benjamin (b) (6) ; btolman (b) (6) >;
Tountas, Karen (FNIH) [T] (b) (6) >; Wachtel, Jonathan (b) (6) >; Wholley, David (FNIH) [T]
(b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) ; Austin, Christopher (NIH/NCATS) [E]
(b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) >; Carluccio, Dana
(b) (6) >; Castillejos, Carlos (b) (6) FNIH Central Account
< (b) (6) Hallett, Adrienne (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E]
(b) (6) ; Myles, Renate (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E]
(b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Wolinetz, Carrie (NIH/OD) [E]
(b) (6) >; Meltzer, Abbey (FNIH) [T] (b) (6)
Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time.** The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting

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(b) (6) US (San Jose)
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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/8/2020 1:56:10 AM
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]
Subject: Follow up to ACTIV Therapeutics-Clinical Working Group Meeting 08/06/2020
Attachments: 2020-08-06_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary for our Working Group meeting yesterday. Thank you all for a good discussion on the next steps for the agents and how we can help to promote and enhance our master protocols.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

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Subject: Initial Follow-up to ACTIV TX-Clinical Working Group Meeting #9

Dear ACTIV TX-Clinical WG,

Thank you all for the good discussion and feedback on the master protocols on today's call.

As promised as part of my initial follow up to the meeting, please find below the now active link for agent survey submissions.

<https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&>

Please feel free to use this for any agents your companies may wish to have considered or share it with any other colleagues who think may have something interesting for us to consider.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish
 [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
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 [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E]
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
 [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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 DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bafd32930-walkerp1]; Colvis, Christine
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
[(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
[(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
[(b) (6) Tolman, Brett [(b) (6) Alvarez, Rosa [(b) (6) Dana
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Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Stratton, Benjamin [(b) (6)
[(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E]
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) (b) (6) USARMY DOD JPEO CBRND (USA) [(b) (6) Elsaid, Olivia [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes [(b) (6) Sorosa, Alex David [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]

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(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas
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[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin
[(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria
[(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael
[(b) (6) Rose Li [(b) (6) Dana Carluccio
[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [(b) (6) Mason, Stephen [(b) (6) Connelly, Sarah [(b) (6)

Location: <https://fnih.zoom.us/> (b) (6)

Start: 10/21/2020 2:15:00 PM

End: 10/21/2020 3:00:00 PM

Show Time As: Tentative

Recurrence: (none)
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) : (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; (b) (6) USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Optional Attendees: (b) (6) (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

From: Connelly, Sarah [(b) (6)]
Sent: 11/6/2020 2:29:28 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
 (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
 (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
 (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
 (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Diamond, Michael [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi
Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio
(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
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Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6) (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical working group,

Next week's full working group meeting falls on Veterans Day. Would the group prefer keeping the meeting on Wednesday at its regularly scheduled time or moving it to 10-11 ET Thursday, Nov 12, 2020?

Can you please let us know which of these options work for you. We will move the meeting to the most popular option.

Best regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine
(NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6)

(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

(b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc
(NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T];
Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah
(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)

[T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah;

(b) (6)

Subject: ACTIV Preclinical full working group

When: Thursday, November 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us> (b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

(b) (6) US (Germantown)

(b) (6) US (Chicago)

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US (San Jose)

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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us>, (b) (6)

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GADB0000001846-2516914

From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]

Sent: 10/22/2020 1:39:56 PM

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];
(b) (6) (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa];
(b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
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Subject: Re: ACTIV Preclinical full working group

ACTIV Preclinical WG –

(b) (4)

Thanks!

Clint Florence, Ph.D.
Program Officer, Office of Biodefense, Research Resources, and Translational Research
NIH/NIAID/DMID/OBRTR/RRS
Room 8G56
5601 Fishers Lane
Rockville, MD 20852
Tel: (b) (6)
cell: (b) (6)

From: "Florence, Clint (NIH/NIAID) [E]" <(b) (6)>
Date: Wednesday, October 21, 2020 at 12:47 PM
To: "Menetski, Joseph (FNIH) [T]" (b) (6) "john." (b) (6)
<(b) (6)> "kara." (b) (6) <(b) (6)> "Hild, Sheri (NIH/OD) [E]" <(b) (6)> " (b) (6) <(b) (6)>
" (b) (6) <Anna (b) (6) " (b) (6)
<(b) (6) " (b) (6) <(b) (6) "Baric, Ralph" <(b) (6)
" (b) (6) <(b) (6) "Ottinger, Elizabeth (NIH/NCATS [E]"
<(b) (6) "Colvis, Christine (NIH/NCATS) [E]" <(b) (6) "Hewitt, Judith (NIH/NIAID) [E]" <(b) (6) "Deming, Damon (FDA/CDER)" <(b) (6)
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<(b) (6) "Rao, Srinivas" <(b) (6) "Qashu, Felicia (NIH/OD) [E]"
<(b) (6) Tomas Cihlar <(b) (6) "Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)" <(b) (6) "Punturieri, Antonello (NIH/NHLBI) [E]"
<(b) (6) "Charette, Marc (NIH/NHLBI) [E]" <(b) (6) "Fessel, Josh (NIH/NHLBI) [E]" <(b) (6) " (b) (6) <(b) (6)
" (b) (6) <(b) (6) " (b) (6)
<(b) (6) "Wholley, David (FNIH) [T]" <(b) (6) "Austin, Christopher (NIH/NCATS)

[E]" < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6) "Colvis, Christine
(NIH/NCATS) [E]" < (b) (6) "Desrosiers, Betsy" < (b) (6) Eric
Hughes < (b) (6) "Jansen, Kathrin" < (b) (6) "Kurilla, Michael
(NIH/NCATS) [E]" < (b) (6) "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah
(NIH/NIAID) [E]" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6) "Santos, Michael
(FNIH) [T]" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "James, Stephanie (FNIH) [T]"
< (b) (6) "Alvarez, Rosa Maria" < (b) (6) "Kim, Elizabeth"
< (b) (6) btolman < (b) (6) "Wachtel, Jonathan" < (b) (6)
Prabhavathi Fernandes < (b) (6) "Diamond, Michael" < (b) (6)
Rose Li < (b) (6) Dana Carluccio < (b) (6) "Lagos,
Enrique (NIH/NCATS) [E]" < (b) (6) "Jonson, Samantha (NIH/NCATS) [E]"
< (b) (6) "Gonzalez, Nina" < (b) (6) "Simon, Dina (NIH/OD) [C]"
< (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" < (b) (6) "Rodriguez, Robin
D" < (b) (6) Dave Frankowski < (b) (6) "Baric, Toni C"
< (b) (6) "Lowy, Douglas (NIH/NCI) [E]" < (b) (6) "Florence, Clint
(NIH/NIAID) [E]" < (b) (6) Nancy Haigwood < (b) (6) "Stratton, Benjamin"
< (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Anderson, James
(NIH/OD) [E]" < (b) (6) "Hawk, Harrison" < (b) (6) "Mason, Stephen"
< (b) (6) "Connelly, Sarah" < (b) (6) "
< (b) (6)

Subject: Re: ACTIV Preclinical full working group

ACTIV Preclinical Group –

(b) (4)

(b) (4)

Thanks –

Clint

From: (b) (6)

When: 10:15 AM - 11:00 AM October 21, 2020

Subject: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Dial by your location

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US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 7/23/2020 8:52:26 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)] Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)] Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)] Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)] Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6)] Vincent, Mike [(b) (6)] Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]
CC: Wachtel, Jonathan [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)] Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)] Ardiff, Bernadette [(b) (6)] Criffield, Robin [(b) (6)] Hamilton, Nancy [(b) (6)] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [bminnich@fredhutch.org]; Mueller-Reichenstein, Petra [(b) (6)] Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [(b) (6)] m]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)] Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)] James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange

(b) (6) US (Tacoma)
Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Young, John [(b) (6)]
Sent: 6/6/2020 8:19:31 AM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
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(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
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(b) (6) Kim, Elizabeth [(b) (6)] Tolman, Brett [(b) (6)] Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael
[(b) (6) Rose Li [(b) (6) Dana Carluccio
[(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos];
Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
(b) (6)]; Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: Re: ACTIV Preclinical working group (Tuesday meeting)

Hi Joe

Minutes look good. No major comments from my side.

We will need to identify owner(s) of the literature review action item at our next meeting.

Best regards

John

On Fri, Jun 5, 2020 at 8:28 PM Menetski, Joseph (FNIH) [T] (b) (6) wrote:

Dear Preclinical working group and attendees,

Please find the minutes from the meeting on Wednesday. Thank you for an interesting meeting and let me know if you have any questions or comments on the notes.

Thank you,

Joe

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T]

Sent: Tuesday, April 14, 2020 6:43 PM

To: (b) (6) (b) (6) ; Rao, Srinivas;
(b) (6) Punturieri, Antonello (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Menetski,
Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)
(b) (6) (b) (6) ; (b) (6) (b) (6)
(b) (6) (b) (6) ;
(b) (6) (b) (6) (b) (6) Parker, Ashley

(NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]

Cc: Florence, Clint (NIH/NIAID) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, June 3, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

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--

John A.T. Young, PhD

VP and Global Head Infectious Diseases

Immunology, Infectious Diseases and Ophthalmology (I2O) Discovery and Translational Area

Roche Pharma Research & Early Development

Roche Innovation Center Basel

F.Hoffmann-La Roche Ltd

Grenzacherstrasse 124

4070 Basel, Switzerland

Phone (b) (6)

Mobile

Mail to

Assistant:

Gianni Micheloni

Phone (b) (6)

Mobile

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From: Connelly, Sarah [(b) (6)]
Sent: 1/21/2021 6:19:04 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m;
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabhavathi Fernandes [(b) (6) Diamond, Michael [(b) (6) Rose Li

[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[(b) (6) Dave Frankowski [(b) (6) antoinette_baric
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6) (b) (6) (b) (6)
Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Lloyd
[(b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: 2020_NIH_Antiviral_Summit_Report_508.pdf; 2021-01-20_Preclinical_WG_vF.pdf; Preclinical WG_Subgroup Updates.pptx

Dear Preclinical Working Group,

Thank you all for attending our ACTIV preclinical full working group meeting yesterday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments. We have also attached a slide with the subgroup updates we didn't get to during the meeting.

Also attached please find the finalized report for the SARS-CoV-2 summit on antiviral drug development. Sharing with the WG for awareness.

Best Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)
(b) (6) (b) (6) jay_ (b) (6) (b) (6) Baric, Ralph;
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith
(NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter

(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

(b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah;

(b) (6)

Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b) (6)

(b) (6)

Connelly, Sarah;

Subject: ACTIV Preclinical full working group

When: Wednesday, January 20, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/17/2021 4:42:43 PM
To: Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dc43e785c83411756cd9e7-HarrisKath]; Jessica (NIH/OD) Tucker [E] ((b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0ff5e52c31a4-tuckerjm]
Subject: more on Baric mouse model
Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216_vF.pdf; 02.17.21 ACTIV EC and Leadership Team Meeting_APPENDIX_20210216_vF.pdf; 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.pdf

Slides include Baric's long hauler mouse model and testing plans. John Young is presenting to the Leadership Team now.

From: Melencio, Cheryl (FNIH) [T] < (b) (6) > **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, February 16, 2021 7:03 PM
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Bancel, Stephane
< (b) (6) > Carter, Kara < (b) (6) > Cavaleri, Marco
< (b) (6) > Cihlar, Tomas < (b) (6) > Collins, Francis (NIH/OD) [E]
< (b) (6) > Corey, Larry < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) >
Victoria Davey < (b) (6) > Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) > Dolsten, Mikael
< (b) (6) > Embry, Alan (NIH/NIAID) [E] < (b) (6) > Erbeling, Emily (NIH/NIAID) [E]
< (b) (6) > Erck, Stan < (b) (6) > Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >
Freire, Maria (FNIH) [T] < (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Gibbons, Gary
(NIH/NHLBI) [E] < (b) (6) > Hudson, Thomas < (b) (6) > James, Stephanie (FNIH) [T]
< (b) (6) > Johnson, Robert (OS/ASPR/BARDA) < (b) (6) > Kramer, Lynn
< (b) (6) > Lane, Cliff (NIH/NIAID) [E] < (b) (6) > Lepore, John < (b) (6) >
Marks, Peter (FDA/CBER) < (b) (6) > Mascola, John (NIH/VRC) [E] < (b) (6) > Meeker,
David < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Messonnier, Nancy
(CDC/DDID/NCIRD/OD) < (b) (6) > Pandya, Hitesh < (b) (6) > Pangalos, Mene
< (b) (6) > Pao, William < (b) (6) > Parker, Ashley (NIH/OD) [E]
< (b) (6) > Paul, Steve < (b) (6) > Perlmutter, Roger < (b) (6) >
Plenge, Robert < (b) (6) > Plump, Andy < (b) (6) > Rachel Ramoni
< (b) (6) > Reed, John < (b) (6) > Reese, David < (b) (6) > Rouse, Doris
< (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Skovronsky, Daniel < (b) (6) >
Stein, Peter (FDA/CDER) < (b) (6) > Stoffels, Paul < (b) (6) > Tabak, Lawrence (NIH/OD)
[E] < (b) (6) > Talley, Michael < (b) (6) > Tsai, John < (b) (6) >
Vessey, Rupert < (b) (6) > Virgin, Skip < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) >
Woodcock, Janet (FDA/OC) < (b) (6) > Young, John < (b) (6) > Colvis,
Christine (NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) > Eric
Hughes < (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E]
< (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) >
Young, John < (b) (6) >
Cc: Anderson, James (NIH/OD) [E] < (b) (6) > Burklow, John (NIH/OD) [E] < (b) (6) >
Carluccio, Dana < (b) (6) > Castillejos, Carlos < (b) (6) > Culp, Michelle
(NIH/OD) [E] < (b) (6) > FNIH Central Account < (b) (6) > Gadbois, Ellen (NIH/OD) [E]
< (b) (6) > Hallett, Adrienne (NIH/OD) [E] < (b) (6) > Lumsden, Joanne (NIH/NCATS) [C]
< (b) (6) > Myles, Renate (NIH/OD) [E] < (b) (6) > Wolinetz, Carrie (NIH/OD) [E]
< (b) (6) > Adam, Stacey (FNIH) [T] < (b) (6) > Margaret Anderson
< (b) (6) > Appell, Evan < (b) (6) > Chen, Helen < (b) (6) >
Connelly, Sarah < (b) (6) > Dally, Nicole < (b) (6) > Gonzalez, Nina
< (b) (6) > Hawk, Harrison < (b) (6) > Mendelson, Jesse < (b) (6) >

Menetski, Joseph (FNIH) [T] < (b) (6) Nasr, Hana < (b) (6) Santos, Michael (FNIH) [T]
< (b) (6) Sorosa, Alex < (b) (6) Stratton, Benjamin < (b) (6) Tolman,
Brett < (b) (6) Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T]
< (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Hallett, Adrienne (NIH/OD) [E]
< (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]
< (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time.** The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b) (6) Connelly, Sarah
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Subject: Canceled: ACTIV Preclinical full working group

Start: 3/3/2021 3:00:00 PM

End: 3/3/2021 4:00:00 PM

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Recurrence: (none)

Required Attendees: (b) (6) Hild, Sheri (NIH/OD) [E]; david.j. (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley
 (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia
 (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello
 (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
 (b) (6)

Optional Attendees: Lerner, Andrea (NIH/NIAID) [E]; Gonzalez, Nina; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah; (b) (6) Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; kca (b) (6) Embry, Alan (NIH/NIAID) [E]

The cochairs would like to cancel today and encourage you to join the WHO meeting below.

WHO will host a **Global consultation on COVID-19 therapeutics** to discuss knowledge gaps and research priorities, with the following objectives to outline:

- the main priority research questions of importance to public health and a targeted research agenda for 2021 that identifies knowledge gaps and prioritization pathways for therapeutics in clinical development phase and those being repurposed, including combinations, and research priorities for new COVID therapeutics; and
- additional steps to ensure further international collaboration supports the coordinated implementation of key research.

The webinar will be convened on **Wednesday, 3 March 2021, 13:30 – 18:30 Central European Time (CET)**. The proposed agenda will be provided in advance.

Please register on the link below to receive your connection details.

https://who-e.zoom.us/webinar/register/WN_CNfywAEiTEWgqA_nEcjeow

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/17/2020 4:00:45 PM
To: Garner, Carl [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Eisner, Mark [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Levy, Elliot [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [naimish. (b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)] Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV

DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; [(b) (6) DTRA J9 (USA) [(b) (6) [(b) (6) SARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcbfd32930-walkerp1]; Bethany Stokes [(b) (6) Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Subject: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical WG Meeting_20201217.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 12/17/2020 6:00:00 PM

End: 12/17/2020 7:00:00 PM

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Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required

Attendees:

Garner, Carl; Bozette, Sam (NIH/NCATS) [E]; Butters, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]

Optional

Attendees:

Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6); Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Dear ACTIV TX-Clinical WG Members,

Please find attached the slides for today's presentation.

Thanks,
Stacey

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) Cavalieri Marco [(b) (6) (b) (6) (b) (6) (b) (6) Greg Glenn [(b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f4be4598a57b423d484dcf9f-offit.email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) (b) (6) Tal Zaks [(b) (6) (b) (6) (b) (6) Hopps, Markay [(b) (6) (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey [(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.com/nih/> (b) (6)

Start: 8/14/2020 5:00:00 PM

End: 8/14/2020 6:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell (b) (6) (b) (6) Cavaleri Marco; (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes, Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks

Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Hamilton, Holli (OS/ASPR/BARDA); (b) (6) USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Ann Arvin

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Sent: 7/1/2020 3:39:02 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) (b) (6) (b) (6) (b) (6)
Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Diamond, Michael [(b) (6)

Subject: Re: ACTIV Preclinical full working group

Attachments: 2020.06.20.137687v1.full.pdf

All –

U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant.

In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented.

Might be of benefit in the EXE meeting tonight.

Just an FYI.

Clint

From: (b) (6)

When: 10:00 AM - 11:00 AM July 1, 2020

Subject: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Sent: 6/15/2020 5:04:44 PM
To: (b) (6); (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6); (b) (6); (b) (6); (b) (6); (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Diamond, Michael [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel, Jonathan [(b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical full working group
Attachments: 2020-06-10_Preclinical_WG_Summary_F2.docx

Dear Preclinical working group members and attendees,

Please find the minutes from last weeks meeting attached. Feel free to contact me if you have any questions.

Best regards,
Joe

-----Original Appointment-----

Subject: ACTIV Preclinical full working group
When: Wednesday, June 10, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/21/2020 10:23:41 PM
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CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Garner, Carlos [(b) (6) Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; Reid, Nancy (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=baa8b238107d4c39822dbe4459ff0089-reidnc]; Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Moschetti, Justin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=194d297d48db4292821d286fa89badce-moschettij]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Minnich, Beth [bminn (b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Jintanat Ananworanich [(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_05222020.pdf; ACTIV Protocol Tracker 05212020.pdf
Location: <https://zoom.us/> (b) (6)

Start: 5/22/2020 1:00:00 PM
End: 5/22/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Attendees: Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Qashu, Felicia

Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G]; Moschetti, Justin (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the *All of Us* program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker – thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but

understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Rosenthal, Alex (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0219642585914a38a4ec6566c4992ec8-alexr]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [(b) (6) Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roisenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)

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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 CC: Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
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 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
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 Gonzalez, Nina [(b) (6) Dana Carluccio [(b) (6) Rose Li Central
 Account [(b) (6) Lucas Smalldon [(b) (6) Stratton, Benjamin
 [(b) (6) (b) (6) Mollica, Linda /US [(b) (6) Qashu,
 Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
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 CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
 (b) (6) Elsaid, Olivia [(b) (6) Walker, Paula (NIH/NINDS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes
 [(b) (6) Giovanni, Maria (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange
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 Merritt, Gabriella Marie [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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Start: 10/8/2020 5:00:00 PM
 End: 10/8/2020 6:00:00 PM

Recurrence: (none)

Required Attendees: Rosenthal, Alex (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Dodd, Lori (NIH/NIAID) [E]

Optional Attendees: Merritt, Gabriella Marie; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); (b) (6) USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Giovanni, Maria (NIH/NIAID) [C]

Sent: 6/22/2020 6:52:55 PM
Subject: FW: Notes from our ACTIV Executive Committee call on 6/17/2020
Attachments: 2020-06-17_Executive_Committee_Meeting_Summary vFinal.docx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Monday, June 22, 2020 2:44 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>
Dolsten, Mikael <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary
(NIH/NHLBI) [E] <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Pao, William
<(b) (6)> Plump, Andrew <(b) (6)> Stoffels, Paul <(b) (6)>
Woodcock, Janet (FDA/CDER) <(b) (6)> Colvis, Christine (NIH/NCATS) [E]
<(b) (6)> Desrosiers, Betsy <(b) (6)> Hughes, Eric
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret
<(b) (6)> Chen, Helen <(b) (6)> Elsaid, Olivia <(b) (6)>
Gonzalez, Nina <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH)
[T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Ben <(b) (6)>
Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Togashi, Mieko (NIH/NCI) [E]
<(b) (6)> Underwood, Nancy <(b) (6)> Zottoli, Jessica
<(b) (6)> Barasch, Kimberly (NIH/NIAID) [C] <(b) (6)> Conrad, Patricia
(NIH/NIAID) [E] <(b) (6)> Dimishkov, Roxanne (NIH/NHLBI) [C] <(b) (6)>
McManus, Ayanna (NIH/OD) [E] <(b) (6)> Perala, Mie <(b) (6)> Protasiewicz,
Ann <(b) (6)> Riccobene, Kim <(b) (6)> Thomas, Ashley (FDA/CDER)
<(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E]
<(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burklow, John (NIH/OD) [E]
<(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E]
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Burrus-Shaw, Cyndi (NIH/OD) [E] <(b) (6)> Carver, Trea (NIH) [C]
<(b) (6)> Hardesty, Rebecca (NIH/OD) [E] <(b) (6)> Lagos, Enrique (NIH/NCATS) [E]
<(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Sepulveda, Dorina (FNIH) [T]
<(b) (6)> Simon, Dina (NIH/OD) [C] <(b) (6)>
Subject: Notes from our ACTIV Executive Committee call on 6/17/2020

Dear ACTIV Executive Committee members and meeting attendees:

Please find attached the complete meeting notes from our June 17 teleconference. Action items were previously distributed on June 18. Please let me know any questions or comments.

Regards,
David Wholley

David Wholley

APAR0000028678-2516928

Senior Vice President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/25/2021 5:54:47 PM
To: Levy, Elliot [(b) (6)] Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)] Gottesdiener, Keith [(b) (6)] Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)] LaVange, Lisa [(b) (6)] Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)] Peppercorn, Amanda [(b) (6)] Poole, Mike [(b) (6)] Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6)] Garner, Carl [(b) (6)] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6)] Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai [(b) (6) Wung, Peter K [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-fennellyam]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Subject: ACTIV Therapeutics-Clinical Working Group

Attachments: ACTIV_TX-Clinical WG Meeting_20210225_v1.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 2/25/2021 6:00:00 PM

End: 2/25/2021 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Levy, Elliot; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. See you in a few minutes.

Thanks,
Stacey

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From: Alvarez, Rosa Maria [(b) (6)]
Sent: 7/8/2020 1:13:47 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) [(b) (6)]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) [(b) (6)]; (b) (6) [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) [(b) (6)]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6)]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6)]; Hughes, Eric [(b) (6)]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6)]; Tolman, Brett [(b) (6)]; Wachtel, Jonathan [(b) (6)]; Prabhavathi Fernandes [(b) (6)]; Diamond, Michael [(b) (6)]; Rose Li [(b) (6)]; Dana Carluccio [(b) (6)]; Lagos, Enrique (NIH/NCATS) [(b) (6)]

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject: RE: ACTIV Preclinical full working group

Hi all,

Please see below for today's agenda. Looking forward to our discussion at 10am.

Agenda Topic	Duration	Facilitator
Debrief from Leadership Meeting	5 mins	John Young
Discuss approach for preclinical development of combination therapies	15 mins	Christine Colvis
Debrief on NHP prioritization strategy updates	10 mins	Jim Anderson, Joe Menetski
Discuss potential plan for genotypic monitoring	10 mins	Tomas Cihlar, Marco Salemi
Sub Group Updates	15 mins	Sub Group Leads
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Best regards,
Joe and Rosa

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] < (b) (6) >

Sent: Tuesday, April 14, 2020 6:44 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6); (b) (6);

(b) (6); (b) (6); (b) (6); (b) (6);

(b) (6); (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)

[E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]
Subject: ACTIV Preclinical full working group
When: Wednesday, July 8, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/27/2020 1:20:05 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Hughes, Eric [(b) (6) Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Amanda Peppercorn [(b) (6) Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy [(b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6)]; Kim, Elizabeth [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Wachtel, Jonathan (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tolman, Brett [(b) (6) Alvarez, Rosa Maria [(b) (6) Chen, Helen Q. [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: COVID-19 Status Reports and Dashboards from VA and UC System

Attachments: Copy of DailyReport_20200522.xlsx; UC Report 5-22-20.pdf

Dear ACTIV TX-Clinical Working Group,

Please find attached some initial RWD that the FDA team has been kind enough to give us access to and will update for our group each week if we would find it useful.

Please let me know if either our Agent Prioritization Subgroup or the Master Protocol Subgroup would find this data useful as we are prioritizing agents and planning trials. If so, I will work with Peter Stein to ensure our group gets the updated information at the proper cadence.

Please do not share beyond the ACTIV group at this time.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

From: Stein, Peter <(b) (6)>
Sent: Monday, May 25, 2020 6:59 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)>
Subject: reports

Stacey,
Amy Abernathy is coordinating a group pulling in RWD from a number of sources – with daily reports from the VA and UC system. She has permission to have these shared with the ACTIV group – so I’ve attached reports from last week, and if useful, we can have these at whatever frequency we prefer.

Regards, Peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 9/4/2020 4:44:15 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) Annaliesa. (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adfcdbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim,

Elizabeth [(b) (6)] btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi
Fernandes [(b) (6)] Diamond, Michael [(b) (6)] Rose Li
[(b) (6)] Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6)] Dave Frankowski [(b) (6)] Baric, Toni C
[(b) (6)] Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
Mason, Stephen [(b) (6)] (b) (6)

Subject: ACTIV Preclinical full working group

Location: https://fnih.zoom. (b) (6)

Start: 9/23/2020 2:30:00 PM

End: 9/23/2020 3:30:00 PM

Show Time As: Tentative

Recurrence: Weekly
every Wednesday from 10:00 AM to 11:00 AM

Required Attendees: Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6)
(b) (6) kara. (b) (6) (b) (6) (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) .gov; (b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
(b) (6) ; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E];
Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
Optional Attendees: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine
(NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas
(NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T];
James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi
Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha
(NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D;
Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood;
Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;
(b) (6)

Changing time for this meeting at the request of the cochair.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Timothy Burgess [(b) (6)]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6)]; Butterson, Joan [(b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6)]; Draghia-Akli, Ruxandra [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [(b) (6)]; Judy Currier [(b) (6)]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Mellors, John W [(b) (6)]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [(b) (6)]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [(b) (6)]; Santos, Michael (FNIH) [T] [(b) (6)]; Shen, Yuan Li (FDA/CDER) [(b) (6)]; Stein, Peter (FDA/CDER) [(b) (6)]; Wholley, David (FNIH) [T] [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6)]; Collins, Sylva (FDA/CDER) [Sylva. (b) (6)]; Amanda Peppercorn [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [(b) (6)]; Reineck, Lora (NIH/NHLBI) [E] [(b) (6)]; Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6)]; Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6)]; .gov]; Goff, David (NIH/NHLBI) [E] [(b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisell]; Culp, Michelle (NIH/OD) [E] [(b) (6)]; Jacqueline Kirchner [(b) (6)]; Beigel, John (NIH) [E] [(b) (6)]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6)]; Petrovick, Martha - 0449 - MITLL [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [(b) (6)]; [(b) (6)]; [(b) (6)]; [(b) (6)]; [(b) (6)]; Feltquate, David [(b) (6)]; Larry Tsai [(b) (6)]; Levy, Elliot [(b) (6)]; Garner, Carl [(b) (6)];

CC: Chen, Helen Q. [(b) (6)]; Sorosa, Alex David [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Jansen, Kathrin [(b) (6)]; Lowy, Douglas (NCI) [(b) (6)]; Young, John [john. (b) (6)]; Biggs, Mary [(b) (6)]; Butcher, Tina [(b) (6)]; Demarcus [(b) (6)]; Macone, Erin [(b) (6)]; Melencio, Cheryl (FNIH) [T] [(b) (6)]; Salathin, Carla [carla. (b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6)]; Dana Carluccio [dana.ca (b) (6)]; Rose Li Central Account [(b) (6)]; Lucas Smalldon [(b) (6)]; Mollica, Linda /US [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [(b) (6)]; Patterson, Amy (NIH/NHLBI) [E] [(b) (6)]; Rubin, Daniel B. (FDA/CDER) [(b) (6)]; Marston, Hilary (NIH/NIAID) [E] [(b) (6)]; Wung, Peter /US [(b) (6)]; Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6)]; Groesch, Mary (NIH/NHLBI) [E] [(b) (6)]; Shipp, Allan (NIH/NHLBI) [E] [allan. (b) (6)]; Kindzelski, Andrei (NIH/NHLBI) [E] [(b) (6)]; Hone, David M (Dave) CIV DTRA J9 (USA) [david.m. (b) (6)]; Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)]; Lerner, Andrea (NIH/NIAID) [E] [(b) (6)]; Embry, Alan (NIH/NIAID) [E] [(b) (6)]; LEVINE, MICHAEL [(b) (6)]; Armstrong, Linda [I (b) (6)]

Start: 2/4/2021 6:00:00 PM
End: 2/4/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Burgess, Timothy; Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda

Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; (b) (6) DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6); Sizemore, Christine (NIH/FIC) [E]; (b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

Feltquate, David; Larry Tsai

**Optional
Attendees:**

Chen, Helen Q.; Sorosa, Alex David; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; (b) (6) DTRA J9 (USA); (b) (6) USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; LEVINE, MICHAEL; Armstrong, Linda

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Mellors, John W (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Proshan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli,

Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith
 (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth
 [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364];
 Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaa06ebd70-parkeras];
 Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike
 [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham];
 Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T]
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim
 (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn
 [(b) (6) Garner, Carl [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter
 (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-roosenbey]; Goff, David (NIH/NHLBI) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
 [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; (b) (6)
 DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6)
 (b) (6)
 CC: Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Kurilla,
 Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Tolman, Brett
 [(b) (6) Alvarez, Rosa [(b) (6) Margaret Anderson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Stratton, Benjamin
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.
 [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Elsaid, Olivia
 [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerp1]; Sorosa, Alex David
 [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
 Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
 [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
 (b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio
 (b) (6) Rose Li Central Account [(b) (6) Margaret Anderson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon
 (b) (6) ; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; (b) (6) Mollica, Linda /US
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bafd32930-walkerpl]; Bethany Stokes [(b) (6) asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20201029.pdf

Location: <https://fnih.zoom.us/> (b) (6)

Start: 10/29/2020 5:00:00 PM

End: 10/29/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting in 20 minutes.

Thanks,

GADB0000004238-2516935

Stacey

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To: Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7adadfcdb42cbb4014d9b26af30cc-jhewitt]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Hewitt, Judith (NIH/NIAID) [E] (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; ken.duncan@gatesfoundation.org; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; (b) (6) (b) (6) (b) (6) (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6)

CC: Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6) Tolman, Brett [(b) (6) Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
 [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
 [(b) (6) Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski
 [(b) (6) Baric, Toni C [(b) (6) Lowy, Douglas (NIH/NCI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Stratton, Benjamin
 [(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Rodriguez, Robin D
 [rmdaigle@tulane.edu]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Eric Hughes
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Caroline Sferrazza
 [(b) (6) Diamond, Michael (b) (6)

Subject: ACTIV Preclinical full working group

Location: https://fnih.zoom.us/ (b) (6)

Start: 7/29/2020 2:00:00 PM

End: 7/29/2020 3:00:00 PM

Recurrence: (none)

Required Attendees: Adams, Peter (OS/ASPR/BARDA); (b) (6) (b) (6) Collins, Francis (NIH/OD)
 [E]; (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6)
 (b) (6) : (b) (6) (b) (6) (b) (6)
 (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley
 (NIH/OD) [E]; (b) (6) Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt,
 Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc
 (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)

Optional Attendees: Diamond, Michael; Nancy Haigwood; Rodriguez, Robin D; Austin, Christopher (NIH/NCATS) [E]; Hughes, Eric;
 Anderson, James (NIH/OD) [E]; Caroline Sferrazza; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Colvis,
 Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI);
 Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James,
 Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes;
 Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon,
 Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];
 Florence, Clint (NIH/NIAID) [E]; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/12/2020 12:48:32 PM
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Subject: Summary of the ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical WG,

Please find attached the summary of our meeting on Thursday. If you have any additions or amendments, please be sure to send them my way.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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Subject: Agenda and notes for ACTIV Vaccines Working Group meetings
Attachments: 2021-02-18 Vaccines Working Group meeting Summary Notes.docx; ACTIV TRACE Slides v5.pptx

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The topic for this meeting is a discussion of what information we need to acquire before adding vaccination against a variant strain to a country/region's vaccination strategy. Doug will initiate the conversation then invite perspectives from the participants.

Notes from Thursday's meeting are attached. We sincerely thank Penny and Alex for their presentations on the implications of the 501Y.V2 variant for natural and vaccine-derived immunity and the cross-neutralization of responses to 501Y.V2 infections against ancestral virus. In addition, Joe Menetski's slides on the new ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) Working Group are attached, and anyone interested in more information or participating should feel free to reach out to Joe (b) (6).

We welcome additional comments and questions any time.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, February 17, 2021 6:25 PM
Subject: Agendas and notes for ACTIV Vaccines Working Group meetings

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Thursday) at 2pm ET / 11am PT / 8pm CET.

The topic for this meeting will be antibody immunity to 501Y.V2 through vaccination and infection, with presentations from Penny Moore (South Africa's National Institute of Communicable Diseases) and Alex Sigal (Africa Health Research Institute).

Our third meeting on the topic of viral variants will be Monday, 22 Feb. The agenda for that meeting is a discussion of what information we need to acquire before adding vaccination against a variant strain to a country/region's vaccination strategy. Doug will initiate the conversation then invite perspectives from the participants.

Notes from our first meeting on this topic are attached, with appreciation again to Trevor Bedford and Jesse Bloom and for the many contributions of meeting participants.

Finally, we wanted to provide an update on the concept of a trial to assess the impact of vaccination on infection transmission and viral load, which we discussed in meetings in late 2020. A modified version of the protocol that we discussed has been supported to move forward. The trial plans to enroll 12,000 students including at HBCUs, split between immediate-vaccination and delayed-vaccination arms (substituting delayed vaccination for placebo eased regulatory requirements), with daily viral sampling and contact tracing of infections as possible.

As always, please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, February 11, 2021 2:59 PM
Subject: Slides from today's ACTIV Vaccines Working Group meeting

Hi all,

Thanks again to Trevor and Jesse for their insightful presentations and to everyone who participated in the meeting. Trevor and Jesse have kindly made their slides available at:

- <https://bedford.io/talks/sars-cov-2-molecular-evolution-activ/#/> (advance with space-bar or arrows)
- https://slides.com/jbloom/sars-cov-2_activ

We will be following up with meeting notes, and will send an invite for our next meeting as soon as we can.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, February 9, 2021 5:54 PM
Subject: Agenda for the next ACTIV Vaccines Working Group meeting (Thurs, 11 Feb)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Thursday at 11:30am ET / 8:30am PT / 5:30pm CET. Please note that this meeting is scheduled for 75 min to allow for more discussion.

The topic for this meeting (and planned subsequent meetings) is the evolution of viral variants and the implications for vaccines. For our meeting Thursday, Jesse Bloom and Trevor Bedford of Fred Hutch will join us to present on the genetics of the epidemic and predictive analytics, followed by discussion during which we welcome participants to share the activities that their organizations are undertaking in response.

As always, please reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, December 13, 2020 7:11 PM
Subject: Agenda for the next ACTIV Vaccines Working Group meeting (Monday, 14 Dec)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The main agenda item for tomorrow is discussion of potential approaches to evaluate the impact of vaccines on transmission. This topic was presented and discussed at the 18 Nov meeting of the Vaccines Clinical Trials Sub-Group. If you were unable to join that meeting (or to refresh your memory), the notes with presentation materials embedded are attached.

If we have additional time after that discussion, we may discuss Working Group member perspectives on the other topics that have been discussed recently in the Clinical Trials Sub-Group: the potential for blinded cross-over within studies (30 Nov, notes attached) and evaluating vaccines in immunocompromised populations (10 Dec, notes still to come).

If you cannot join the meeting but would like to provide input on any of the topics above, please send it to us prior to Wednesday, when Doug will be reporting on behalf of the group to the ACTIV Leadership Team.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, November 18, 2020 7:13 PM
Subject: Notes from the ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

With apologies for the delay, attached are notes and the single slide from last week's Vaccines Working Group meeting.

After the meeting, the Working Group and Sub-Group leadership aligned on the immediate priorities for discussion. Those begin today with the Vaccine Clinical Trial Sub-Group's meeting on evaluating the impact of vaccines on transmission. Topics prioritized for subsequent discussions include potential blinded cross-over for ongoing phase 3 trials, preparing for the possibility of vaccine efficacy varying by platform/product, and evaluating vaccines in immunocompromised populations. Invitations for meetings on those topics will be sent soon.

As always, we welcome addition comments and questions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, November 10, 2020 1:33 PM
Subject: Agenda for tomorrow's ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 1pm ET / 10am PT / 7pm CET. We scheduled this meeting last week without knowledge of yesterday's exciting announcement, and are delighted to be re-convening this group at such an auspicious time.

As we described below, the agenda for tomorrow is an open discussion of the priorities for vaccines in addition to the licensure studies that the Vaccines Working Group or the Clinical Trials Sub-Group should consider. Some members of the group have already proposed a few ideas, and all members of the group are invited to make additional suggestions and weigh in on the potential opportunities. After the meeting we will prioritize next steps.

If you cannot attend tomorrow's meeting, as always please feel free to submit ideas in advance that we can share on your behalf or send feedback on the notes afterwards.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Friday, November 6, 2020 1:01 PM
Subject: Next ACTIV Vaccines Working Group meeting: Weds, 11 Nov

Dear Vaccines Working Group members,

As you may recall from the summer, we agreed to stop regular meetings of the Vaccines Working Group and reconvene as needed. Our next meeting will be Wednesday, 11 Nov, at 1pm ET (10am PT / 7pm CET).

We've been requested by ACTIV leadership to have a discussion about the priorities for vaccines in addition to the licensure studies. The Vaccines Clinical Trials Sub-Group has had previous meetings on the topics of evaluation in pregnant and pediatric populations, and is planning upcoming conversations about studying impact on transmission and evaluation in immunocompromised populations, as well as a discussion of the potential application of expanded access protocols.

At our next Working Group meeting, we would appreciate input on those and other potential priorities for discussion within the group. We are looking forward to your thoughts, and as always appreciate any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) | fniih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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[(b) (6) Kathleen Callahan [(b) (6)

Subject: ACTIV Vaccines Working Group meeting

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Start: 7/22/2020 5:30:00 PM

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Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) Seals, Jonathan
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Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
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Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 1/12/2021 9:53:35 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] (b) (6); Carter, Kara [(b) (6)] Cavaleri, Marco [(b) (6)] Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6)] Corey, Larry [(b) (6)] Culp, Michelle (NIH/OD) [E] [(b) (6)] Victoria Davey [(b) (6)] Disbrow, Gary (OS/ASPR/BARDA) [(b) (6)] Dolsten, Mikael [(b) (6)] Erbeling, Emily (NIH/NIAID) [E] [(b) (6)] Erck, Stan [(b) (6)] Gadbois, Ellen (NIH/OD) [E] [(b) (6)]; Gibbons, Gary (NIH/NHLBI) [E] [(b) (6)] Hudson, Thomas [(b) (6)] James, Stephanie (FNIH) [T] [(b) (6)] Johnson, Robert (OS/ASPR/BARDA) [(b) (6)] Kramer, Lynn [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [(b) (6)] Mascola, John (NIH/VRC) [E] [(b) (6)] Meeker, David [(b) (6)] Menetski, Joseph (FNIH) [T] [(b) (6)] Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6)] Pandya, Hitesh [(b) (6)] Pao, William [(b) (6)] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Perlmutter, Roger [(b) (6)] Plenge, Robert [(b) (6)] Plump, Andy [(b) (6)] Reese, David [(b) (6)] Rouse, Doris [(b) (6)] Santos, Michael (FNIH) [T] [(b) (6)] Skovronsky, Daniel [(b) (6)] Stein, Peter (FDA/CDER) [(b) (6)] Stoffels, Paul [(b) (6)] Tabak, Lawrence (NIH/OD) [E] [(b) (6)] Talley, Michael [(b) (6)] Tsai, John [(b) (6)] Vessey, Rupert [(b) (6)] Virgin, Skip [(b) (6)] Wholley, David (FNIH) [T] [(b) (6)] Woodcock, Janet (FDA/OC) [(b) (6)] Young, John [(b) (6)] Anderson, James (NIH/OD) [E] [(b) (6)] Burklow, John (NIH/OD) [E] [(b) (6)] Carluccio, Dana [(b) (6)] Castillejos, Carlos [(b) (6)] FNIH Central Account [(b) (6)]; Hallett, Adrienne (NIH/OD) [E] [(b) (6)] Lumsden, Joanne (NIH/NCATS) [C] [(b) (6)]; Myles, Renate (NIH/OD) [E] [(b) (6)] Wolinetz, Carrie (NIH/OD) [E] [(b) (6)] Colvis, Christine (NIH/NCATS) [E] [(b) (6)] Desrosiers, Betsy [(b) (6)]; Eric Hughes [eric. (b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [(b) (6)] Lowy, Douglas (NCI) [(b) (6)] Read, Sarah (NIH/NIAID) [E] [(b) (6)] Meltzer, Abbey (FNIH) [T] [(b) (6)] Adam, Stacey (FNIH) [T] [(b) (6)] Margaret Anderson [(b) (6)] Appell, Evan [(b) (6)] Chen, Helen [(b) (6)] Connelly, Sarah [(b) (6)] Gonzalez, Nina [(b) (6)] Hawk, Harrison [(b) (6)]; Mendelson, Jesse [(b) (6)] Nasr, Hana [(b) (6)] Sorosa, Alex [(b) (6)] Stratton, Benjamin [(b) (6)] btolman [(b) (6)] Wachtel, Jonathan [(b) (6)] Embry, Alan (NIH/NIAID) [E] [(b) (6)] Venkayya, Rajeev [(b) (6)] Bancel, Stephane [(b) (6)] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John [(b) (6)] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pangalos, Mene [(b) (6)] Paul, Steve [(b) (6)] Ramoni, Rachel [(b) (6)] Reed, John [(b) (6)]
CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6)] Barasch, Kimberly (NIH/NIAID) [E] [(b) (6)] Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)] Carver, Trea (NIH) [C] [(b) (6)] Caulfied, Anita [(b) (6)] Coan, Amanda [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6)] Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; Edl, Susan [(b) (6)] Fuhrer, Nicole [(b) (6)] Giorgi, Sara [(b) (6)] Hoban, Michelle [(b) (6)] Hoffstetter, Renata (FNIH) [T] [(b) (6)] Iberdemaj, Vaide [(b) (6)] Jenkins, Christine S. [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [(b) (6)] Lever, Susan [(b) (6)] Magbie-Robinson, Kim (NIH/OD) [C] [kim. (b) (6)] Martin, Melisa [(b) (6)] McManus, Ayanna (NIH/OD) [E] [(b) (6)]; Minnich, Beth

[(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann
[(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6)
Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda,
Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Suhana, Tina (NIH/VRC)
[E] [(b) (6) .gov]; Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD)
[E] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6) ; Togashi, Mieko (NIH/NCI) [E]
[(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica
[(b) (6) Regan, Donna M [(b) (6) Vessey, Rupert
[(b) (6)]; Burke, Leslie [(b) (6) John Lepore [(b) (6)
Lowy, Douglas (NIH/NCI) [E] [(b) (6) Grant, Sarah [(b) (6) Pruitt, Kim
(NIH/NLM/NCBI) [E] [(b) (6) Sherry, Steve (NIH/NLM/NCBI) [E] [(b) (6) Bell,
Julie (b) (6)

Subject: ACTIV Leadership Team Call #14

Attachments: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, March 18, 2021

Location: <https://fnih.zoom.us/> (b) (6)

Start: 3/18/2021 2:30:00 PM

End: 3/18/2021 4:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; (b) (6)

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Vessey, Rupert; Burke, Leslie; John Lepore; Lowy, Douglas (NIH/NCI) [E]; Grant, Sarah; Pruitt, Kim (NIH/NLM/NCBI) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/16/2021 12:44:39 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]

Subject: Summary of the ACTIV Therapeutics-Clinical Working Group

Attachments: 2021-01-14_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Thank you all for a very good discussion yesterday on the potential path forward for testing additional widely available agents. Please find attached the summary of the meeting if you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Foundation for the National Institutes of Health

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To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Mellors, John W (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Proshan, Michael (NIH/NIAID) [E] [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Levy, Elliot [(b) (6) Jacqueline Kirchner [(b) (6) Garner, Carl [(b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith

[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6) LaVange, Lisa [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd5cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Colli]; Amanda Peppercorn [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Gonzalez, Nina [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Tountas, Karen (FNIH) [T]

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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Alvarez, Rosa [(b) (6) Stratton, Benjamin [(b) (6)
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Elsaid, Olivia
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03b3cf32930-walkerp1]; Kurilla, Michael
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Merritt, Gabriella Marie
 [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; (b) (6)
 Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Freire, Maria (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Desrosiers, Betsy
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 Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6)
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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Rose Li Central Account [(b) (6) Lucas Smalldon
 [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Required Attendees: Levy, Elliot; Jacqueline Kirchner; Garner, Carl; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]
Optional Attendees: Merritt, Gabriella Marie; Margaret Anderson; Gonzalez, Nina; Kurilla, Michael (NIH/NCATS) [E]; (b) (6) Stock, Thomas (HHS/IOS); Freire, Maria (FNIH) [T]; Desrosiers, Betsy; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

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Please find attached the slides for today's presentation.

Thanks,
Stacey

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(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
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Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
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Subject: Summary of ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: 2020-10-22_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG Members,

Please find a summary of the meeting yesterday. Thank you all for a great discussion. If you have any additions or amendments, please let me know!

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Chen, Helen Q. [(b) (6)]
Sent: 9/10/2020 4:44:39 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6)]; Eisner, Mark [(b) (6)]; Gottesdiener, Keith [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth [(b) (6)]; LaVange, Lisa [(b) (6)]; Levy, Elliot [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish [(b) (6)]; Peppercorn, Amanda [(b) (6)]; Poole, Mike [(b) (6)]; Proshan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Amanda Peppercorn [(b) (6)]; Garner, Carl [(b) (6)]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96c8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetz]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner

[(b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [(b) (6) Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John [(b) (6) Biggs, Mary [(b) (6) Butcher, Tina [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [(b) (6) Rose Li Central Account [(b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; [(b) (6) Mollica, Linda /US [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Wung, Peter /US [(b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; [(b) (6) CIV DTRA J9 (USA) [(b) (6) [(b) (6) CTR USARMY DOD JPEO CBRND (USA) [(b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]

Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide_20200910.pdf

Dear ACTIV TX-Clinical Working Group Members,

Please find attached the presentation for our meeting at 1pm ET. Looking forward to speaking with you all soon!

Warm regards,
Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; (b) (6) CIV DTRA J9 (USA); (b) (6) USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom>. (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From: Salemi, Marco [(b) (6)]
Sent: 7/1/2020 8:26:29 PM
To: Rappaport, Jay (b) (6) ; Tomas Cihlar [(b) (6)] ; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieri]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) m; (b) (6) ; (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; (b) (6) USARMY MEDCOM USAMRIID (USA) [(b) (6)] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [(b) (6) Kim, Elizabeth [(b) (6)] Tolman, Brett [(b) (6)] Wachtel,

Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li
[(b) (6) Dana Carluccio [(b) (6)]; Lagos, Enrique (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Jonson, Samantha
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
[(b) (6) Dave Frankowski [(b) (6) Baric, Toni C
[(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
[(b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm];
(b) (6) Diamond, Michael [(b) (6)

Subject: Re: ACTIV Preclinical full working group

Dear Tom,

we also have been monitoring mutations in CoV-2 isolates with some of our in house tools and we are certainly very interested. We have algorithms to test selection pressure, as well as collaborations with structural biology groups that have been mapping mutations on 3D structures. It would be great if we could come up with a comprehensive tool capable of implementing all these different analyses.

Concerning, specifically, the D614G mutations, our statistical analyses on its association to higher mortality do not seem to show a clear effect, although the analyses are certainly affected by sampling bias and the fact that sequences currently available in databases are not sufficiently annotated (e.g., for most of them, we do not have clinical metadata on the infected patients).

As of right now, most mutations seem to accumulate through random genetic drift followed by founder effects, but of course the situation could quickly change, as soon as selective pressure exerted by drugs will start acting on the virus. Having tools capable of effectively monitoring mutation frequencies in populations under different selective constraints will certainly be crucial to detect and monitor possible emergence of drug-resistant or more virulent strains.

Best,

Marco

=====
Marco Salemi, Ph.D.
Professor in Experimental Pathology
Holloway and McClamma Chair
Department of Pathology, Immunology and Laboratory Medicine
University of Florida College of Medicine

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From: Rappaport, Jay <(b) (6)>

Sent: Wednesday, July 1, 2020 2:21 PM

To: Tomas Cihlar <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E]; Florence, Clint (NIH/NIAID) [E]; Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6); (b) (6); (b) (6); (b) (6); Baric, Ralph; (b) (6); Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6); Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6); (b) (6); Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; (b) (6); Diamond, Michael

Cc: Salemi,Marco

Subject: Re: ACTIV Preclinical full working group

[External Email]

Thomas,

This is a very interesting question. Marco Salemi has a very large collection of CoV-2 viral sequences globally and is an expert in viral evolution. Perhaps he can comment.

Best,

Jay

Jay Rappaport

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From: Tomas Cihlar <(b) (6)>

Sent: Wednesday, July 1, 2020 1:14:09 PM

To: Rappaport, Jay <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E] <(b) (6)> Florence, Clint (NIH/NIAID) [E] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Hild, Sheri (NIH/OD) [E] <(b) (6)> (b) (6) <(b) (6)> <(b) (6)> <(b) (6)> <(b) (6)> <(b) (6)> <(b) (6)> <(b) (6)> <(b) (6)> Baric, Ralph <(b) (6)> <(b) (6)> <(b) (6)> Ottinger, Elizabeth (NIH/NCATS) [E] <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Hewitt, Judith (NIH/NIAID) [E] <(b) (6)> Deming, Damon (FDA/CDER) <(b) (6)> <(b) (6)> <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> <(b) (6)> <(b) (6)> Adams, Peter (OS/ASPR/BARDA) <(b) (6)> Rao, Srinivas <(b) (6)> Qashu, Felicia (NIH/OD) [E] <(b) (6)> Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) <(b) (6)> Charette, Marc (NIH/NHLBI) [E] <(b) (6)> Fessel, Josh (NIH/NHLBI) [E] <(b) (6)> <(b) (6)> <(b) (6)>

(b) (6) < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin,
Christopher (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis,
Christine (NIH/NCATS) [E] < (b) (6) Desrosiers, Betsy < (b) (6) Hughes,
Eric < (b) (6) Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]
< (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
Tountas, Karen (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]
< (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6)
Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel, Jonathan
< (b) (6) Prabhavathi Fernandes < (b) (6) Rose Li
< (b) (6) Dana Carluccio < (b) (6) Lagos, Enrique (NIH/NCATS) [E]
< (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b) (6) Gonzalez, Nina
< (b) (6) Simon, Dina (NIH/OD) [C] < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
< (b) (6) Rodriguez, Robin D < (b) (6) Dave Frankowski
< (b) (6) Baric, Toni C < (b) (6) Lowy, Douglas (NIH/NCI) [E]
< (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin < (b) (6)
Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)
(b) (6) < (b) (6) Diamond, Michael < (b) (6)

Subject: RE: ACTIV Preclinical full working group

External Sender. Be aware of links, attachments and requests.

Dear all,

Apologies if I state something obvious that has been discussed during today ACTIV meeting as I have been simultaneously listening to the WHO COVID forum and might have missed it.

The point I want to make is about analysis of genetic changes in the CoV2 virus over time. D614G is only one example that caught peoples eye since the prevalence is so obvious now, but other changes in other proteins of the virus might be happening that could potentially be relevant for sensitivity to new drugs that we are/will be triaging. As of now there are more than 50,000 sequences available in public databases worldwide.

My question is whether there would be interest in monitoring CoV2 sequences over time with a focus on genes most relevant as antiviral targets. Gilead has built infrastructure to do this effectively, initially for nsp12 gene because of remdesivir, but we then expanded to some of the other CoV2 genes and through that we first noticed D614G as early as in mid March long before it became highly prevalent. If there is interest, I'd be happy to discuss the genotypic monitoring at one of the future calls.

Thank you,

Tomas

Tomas Cihlar, PhD

Vice President, Virology

Gilead Sciences, Inc.

Office: (b) (6)

Email: (b) (6)

From: Rappaport, Jay < (b) (6) >

Sent: Wednesday, July 01, 2020 8:51 AM

To: Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) > Florence, Clint (NIH/NIAID) [E]

< (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > Hild, Sheri (NIH/OD) [E]

< (b) (6) > (b) (6) < (b) (6) > (b) (6)

jay_grob (b) (6) (b) (6) Baric, Ralph < (b) (6) >

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) > Colvis,

Christine (NIH/NCATS) [E] < (b) (6) Hewitt, Judith (NIH/NIAID) [E] < (b) (6)
Deming, Damon (FDA/CDER) < (b) (6) (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] (b) (6) >;
(b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) Rao, Srinivas
< (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar
< (b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
< (b) (6) Charette, Marc (NIH/NHLBI) [E] < (b) (6) Fessel, Josh
(NIH/NHLBI) [E] < (b) (6) (b) (6) (b) (6) Wholley, David
(FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Melencio,
Cheryl (FNIH) [T] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < christine. (b) (6)
Desrosiers, Betsy < (b) (6) Hughes, Eric < (b) (6) Jansen,
Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Lowy,
Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH)
[T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]
< (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
< (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6)
Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6)
Rose Li < (b) (6) Dana Carluccio < (b) (6) Lagos,
Enrique (NIH/NCATS) [E] < (b) (6) Jonson, Samantha (NIH/NCATS) [E]
< (b) (6) Gonzalez, Nina < (b) (6) Simon, Dina (NIH/OD) [C]
< (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D
< (b) (6) Dave Frankowski < (b) (6) Baric, Toni C
< (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) Nancy Haigwood
< (b) (6) Stratton, Benjamin < (b) (6) Gadbois, Ellen (NIH/OD) [E]
< (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)
Annaliesa. (b) (6) Diamond, Michael < (b) (6)

Subject: [EXTERNAL] Re: ACTIV Preclinical full working group

Clint and Tony, thanks, important observations.

Best,

Jay

From: "Punturieri, Antonello (NIH/NHLBI) [E]" < (b) (6) >

Date: Wednesday, July 1, 2020 at 10:43 AM

To: "Florence, Clint (NIH/NIAID) [E]" < (b) (6) > "Menetski, Joseph (FNIH) [T]"

< (b) (6) > "Hild, Sheri (NIH/OD) [E]" < (b) (6) > " (b) (6) "

<david.j. (b) (6) " (b) (6) < (b) (6) "Rappaport, Jay"

< (b) (6) " (b) (6) <kara. (b) (6) " (b) (6) "

(b) (6) " (b) (6) < (b) (6) "Baric, Ralph" < (b) (6) "

" (b) (6) < (b) (6) "Ottinger, Elizabeth (NIH/NCATS) [E]"

< (b) (6) "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) "Hewitt, Judith

(NIH/NIAID) [E]" < (b) (6) "Deming, Damon (FDA/CDER)" < (b) (6) "

" (b) (6) < (b) (6) " (b) (6) < (b) (6) "Parker,

Ashley (NIH/OD) [E]" < (b) (6) "Collins, Francis (NIH/OD) [E]" < (b) (6) "

" (b) (6) < (b) (6) "Adams, Peter (OS/ASPR/BARDA)"

< (b) (6) "Rao, Srinivas" < (b) (6) "Qashu, Felicia (NIH/OD) [E]"

< (b) (6) Tomas Cihlar < (b) (6) (b) (6) USARMY MEDCOM

USAMRIID (USA)" < (b) (6) "Charette, Marc (NIH/NHLBI) [E]" < (b) (6) "

"Fessel, Josh (NIH/NHLBI) [E]" < (b) (6) " (b) (6) "

< (b) (6) " (b) (6) < (b) (6) "Wholley, David
(FNIH) [T]" < (b) (6) "Austin, Christopher (NIH/NCATS) [E]" < (b) (6) "Melencio,
Cheryl (FNIH) [T]" < (b) (6) "Colvis, Christine (NIH/NCATS) [E]" < (b) (6)
"Desrosiers, Betsy" < (b) (6) "Hughes, Eric" < (b) (6) "Jansen,
Kathrin" < (b) (6) "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) "Lowy,
Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) (6) "Tountas, Karen
(FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]" < (b) (6) "Adam, Stacey (FNIH) [T]"
< (b) (6) "James, Stephanie (FNIH) [T]" < (b) (6) "Alvarez, Rosa Maria"
< (b) (6) "Kim, Elizabeth" < (b) (6) "Tolman, Brett"
< (b) (6) "Wachtel, Jonathan" < (b) (6) Prabhavathi Fernandes
< (b) (6) Rose Li < (b) (6) Dana Carluccio
< (b) (6) "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) "Jonson,
Samantha (NIH/NCATS) [E]" < (b) (6) "Gonzalez, Nina" < (b) (6)
"Simon, Dina (NIH/OD) [C]" < (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" < (b) (6)
, "Rodriguez, Robin D" < (b) (6) Dave Frankowski
< (b) (6) "Baric, Toni C" < (b) (6) "Lowy, Douglas
(NIH/NCI) [E]" < (b) (6) Nancy Haigwood < (b) (6) "Stratton, Benjamin"
< (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Anderson, James
(NIH/OD) [E]" < (b) (6) " (b) (6)
(b) (6) "Diamond, Michael" < (b) (6)

Subject: RE: ACTIV Preclinical full working group

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And convalescent plasma appears to block it as well as the G variant

Tony

From: Florence, Clint (NIH/NIAID) [E] < (b) (6) >

Sent: Wednesday, July 1, 2020 11:39 AM

To: Menetski, Joseph (FNIH) [T] < (b) (6) > Hild, Sheri (NIH/OD) [E] < (b) (6) >

(b) (6) (b) (6) (b) (6) (b) (6)

(b) (6) (b) (6) Baric, Ralph (b) (6) >;

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) > Colvis,

Christine (NIH/NCATS) [E] < (b) (6) > Hewitt, Judith (NIH/NIAID) [E] < (b) (6) >

Deming, Damon (FDA/CDER) < (b) (6) > (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E] < (b) (6) > Collins, Francis (NIH/OD) [E] (b) (6)

(b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) > Rao, Srinivas

< (b) (6) > Qashu, Felicia (NIH/OD) [E] < (b) (6) > Tomas Cihlar

< (b) (6) > Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)

< (b) (6) > Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) > Charette,

Marc (NIH/NHLBI) [E] < (b) (6) > Fessel, Josh (NIH/NHLBI) [E] < (b) (6) >

(b) (6) Frank. (b) (6) Wholley, David (FNIH) [T] < (b) (6) >

Austin, Christopher (NIH/NCATS) [E] < (b) (6) > Melencio, Cheryl (FNIH) [T]

< (b) (6) > Colvis, Christine (NIH/NCATS) [E] (b) (6) Desrosiers, Betsy

< (b) (6) > Hughes, Eric < (b) (6) > Jansen, Kathrin

(b) (6) Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas

(NCI) < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Tountas, Karen (FNIH) [T]

< (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]
< (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
< (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6)
Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6)
Rose Li < (b) (6) Dana Carluccio < (b) (6) Lagos,
Enrique (NIH/NCATS) [E] < (b) (6) Jonson, Samantha (NIH/NCATS) [E]
< (b) (6) Gonzalez, Nina < (b) (6) Simon, Dina (NIH/OD) [C]
< (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D
< (b) (6) Dave Frankowski < (b) (6) Baric, Toni C
< (b) (6) Lowy, Douglas (NIH/NCI) [E] < (b) (6) Florence, Clint
(NIH/NIAID) [E] < (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin
< (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD)
[E] < (b) (6) Annaliesa. < (b) (6) Diamond, Michael
<mdia (b) (6)

Subject: Re: ACTIV Preclinical full working group

All –

U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant.

In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented.

Might be of benefit in the EXE meeting tonight.

Just an FYI.

Clint

From: (b) (6)

When: 10:00 AM - 11:00 AM July 1, 2020

Subject: ACTIV Preclinical full working group

Location: <https://fnih.zoom.us> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.u> (b) (6)

Meeting ID: (b) (6)

Password: (b) (6)

One tap mobile

(b) (6)

US (Germantown)

US (Chicago)

Dial by your location

(b) (6)

US (Germantown)

(b) (6)

US (Chicago)
US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 6/1/2020 10:28:22 PM
To: Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Vincent, Mike [(b) (6) Bascles, Lionel [(b) (6) Corey, Larry [(b) (6) Garner, Carlos [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James [(b) (6) Ferguson, Sue [(b) (6)
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Chen, Jue (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40509dd20ea84f0eb23950b0b208440b-chenj19]; [(b) (6) [(b) (6) [(b) (6) Iturriaga, Erin (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65eb1f37c0a3421eb1186931e4cb5fb6-iturriae]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Pearson, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb1e26f1e264499aa898a482fe0b4045-pearsong]; Lash, Tiffani (NIH/NIBIB) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b05d39abdd5401f98252536c5985269-baileyti]; Merchak, Todd (NIH/NIBIB) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6cf5910b2ab445c80b8f1329ddc0387-merchakt]; Wachtel, Jonathan [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li,
 Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Qashu, Felicia
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Santos, Michael (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy
 [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin
 [(b) (6) Hamilton, Nancy [(b) (6) Hill, Zoe (NIH/NHLBI) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Minnich, Beth
 (b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora
 [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Culp, Michelle (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Kenny, Dermot
 [(b) (6) (b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda_06022020.pdf
Location: <https://fnih.zoom.us/j> (b) (6)

Start: 6/2/2020 1:00:00 PM
End: 6/2/2020 2:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
 every Tuesday from 9:00 AM to 10:00 AM

Required Attendees: Mensah, George; Vincent, Mike; Bascles, Lionel; Corey, Larry; Garner, Carlos; Cohen, Myron; Davey, Victoria;
 Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla,
 Mike; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E];
 Srinivasan, Badhri; Stein, Peter (FDA/CDER); Weinmann, Gail; Kublin MD, MPH, James; Ferguson, Sue

Optional Attendees: Gadbois, Ellen (NIH/OD) [E]; Chen, Jue (NIH/NHLBI) [E]; (b) (6)
 (b) (6) (b) (6) (b) (6) Iturriaga, Erin
 (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Pearson, Gail (NIH/NHLBI) [E]; Lash, Tiffani (NIH/NIBIB) [E];
 Merchak, Todd (NIH/NIBIB) [E]; Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin;
 Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley
 (NIH/OD) Parker [E] (b) (6) Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6)
 Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos,
 Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Hill, Zoe (NIH/NHLBI)
 [C]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E]
 (b) (6) Culp, Michelle (NIH/OD) [E]; Kenny, Dermot; (b) (6)

Dear Colleagues, Attached is the meeting agenda, we'll be welcoming the RADx team to this meeting and hearing about their activities. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/9/2020 5:28:03 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd2247548e596778304f781f-austinc]; Bright, Rick [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Rouse, Doris [rouse@rti.org]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tsai, John [(b) (6) Vessey, Rupert [(b) (6)]; Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide
[(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Protasiewicz, Ann
[(b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Lagos, Enrique
(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; McManus, Ayanna
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Adam, Stacey (FNIH) [T]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Li, Rose
[rose.l (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Zottoli, Jessica
[Jessica.Zottol (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, Margaret [(b) (6) m]; Robert
Plenge [(b) (6) Stratton, Ben [(b) (6) Alvarez, Rosa [(b) (6)
Kim, Elizabeth [(b) (6) Wachtel, Jonathan (b) (6)]; Tolman, Brett
[(b) (6)

Subject: ACTIV response partnership leadership team meeting #2

Location: <https://zoom.us/> (b) (6)

Start: 4/22/2020 2:00:00 PM

End: 4/22/2020 3:00:00 PM

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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bright, Rick; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; James, Stephanie (FNIH) [T]; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Li, Rose; Tountas, Karen (FNIH) [T]; Zottoli, Jessica; Gonzalez, Nina; Anderson, Margaret; Robert Plenge; Stratton, Ben; Alvarez, Rosa; Kim, Elizabeth; Wachtel, Jonathan; Tolman, Brett

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 8/18/2020 3:11:23 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John

(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [(b) (6) Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd] CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide (b) (6)]; Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan [susan. (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [donna. (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy
 [(b) (6) Zottoli, Jessica | (b) (6)

Subject: ACTIV Leadership Call #9

Location: <https://fnih.zoom.> (b) (6)

Start: 10/21/2020 4:00:00 PM

End: 10/21/2020 5:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/6/2021 6:35:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Speaking to ACTIV-2 today

Hi Francis,

My apologies for the late arrival in your inbox.

Please find below some suggested thoughts for your presentation in 30 minutes. Feel free to any that you feel are appropriate. I think the main point that the team was hoping for is just a strong show of NIH support from the top for all the efforts the sites have been putting in.

Please feel free to revise if needed:

- Appreciate all the dedication, hard work, and long hours contributed to ACTIV-2
- Understand that there have been many challenges to overcome:
 - Challenging routes of drug administration – IV infusions for mAbs
 - Rapid pace of the master protocol for site stand up and regulatory approvals
 - Fast addition of new agents causing continuous updates at the sites
- THANK YOU for your perseverance through all of these
- Congratulations on creating a vast and diverse network to reach patients where they are:
 - Over 150 sites open domestically and 100+ international sites ready to come onboard
 - Successful branding and promotional campaign
 - Continued dedication to reaching underserved communities: Successful deployment of the “Barber Shop” program and others
- Agents being tested are making a difference:
 - Over 1200 patients treated with Lilly’s bamlanivimab EUA authorized agent
 - Brie Bio advancing to Phase 3 testing
 - Brie Bio and AZ mAb cocktails and SAB polyclonal Abs seem to retain potency against the emerging variants of concern
 - Oral (camostat) and inhaled (IFN-beta) antivirals could provide much needed treatments that are not susceptible to the emerging variants

(b) (4)

- Strong desire and collaborative spirit to share what you have learned with other trials to help advance the field

Thanks,
Stacey

Stacey J. Adam, PhD
Associate Vice President
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Tuesday, April 6, 2021 8:17 AM

To: Adam, Stacey (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>

Subject: Speaking to ACTIV-2 today

Hi Stacey and David,

My calendar says I am speaking to the ACTIV-2 PIs today at 3 pm. I think this was supposed to be a “rally the troops” moment, thanking them for their hard work and encouraging continuing efforts. Can you suggest some specific points I should make with these folks?

Thanks, Francis

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 10/15/2020 4:56:47 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaafe06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael [(b) (6) Tsai, John [(b) (6)]; Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

[(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; richard. [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Sorosa, Alex [(b) (6) Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; CC: Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita [(b) (6) Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter]; Iberdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Krack, Kimberly [kimberly]; [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [(b) (6) Perala, Mie [mie.perala@takeda.com]; Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6)

Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy [nan (b) (6) Zottoli, Jessica (b) (6) Regan, Donna M [(b) (6) Hamilton, Nancy [(b) (6) Dana Carluccio [(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowydl]

Subject: ACTIV Leadership Call #9

Location: <https://fnih.zoom.us/> (b) (6)

Start: 10/21/2020 1:15:00 PM

End: 10/21/2020 2:15:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; (b) (6); Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Appell, Evan; Sorosa, Alex; Connelly, Sarah Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Hamilton, Nancy; Dana Carluccio; dee.lowings@astrazeneca.com; Lowy, Douglas (NIH/NCI) [E]

Optional Attendees:

Due to an unavoidable conflict for Dr. Collins, it is necessary to move this call from 12:00 p.m. to 9:15 a.m. Thank you.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/19/2020 5:07:19 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: FW: ACTIV Leadership mtng Thurs 12-1pm
Attachments: ACTIV.leadership.transmission.trial.11.20.pptx

Just fyi, what will be added to the slides shown tomorrow.

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Wednesday, November 18, 2020 9:19 PM
To: Appell, Evan <(b) (6)>
Cc: Gonzalez, Nina <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Subject: FW: ACTIV Leadership mtng Thurs 12-1pm

Hi Evan,

Doug made two slides to discuss the transmission study. Would you mind slotting them in behind the two existing vaccine slides in the version of the deck that will be presented?

Unsurprisingly Doug used a different slide template, but I already let him know the font, colors, etc. would likely be converted to match the rest of the deck, so feel free to make formatting adjustments as desired.

The slides are text-heavy but we don't really have time to iterate (and I think they explain the key points well).

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Wednesday, November 18, 2020 8:43 PM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Johnson, Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C] <(b) (6)> btolman <(b) (6)>
Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike: I ended up making two slides about the proposed protocol (attached). Please get in touch with me if you have concerns/suggestions. Thanks, Doug

From: "Santos, Michael (FNIH) [T]" <(b) (6)>
Date: Wednesday, November 18, 2020 at 3:02 PM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)>
Cc: Maureen Johnson <(b) (6)> "Kozlowski, Mary (NIH/NCI) [C]"
<(b) (6)> <(b) (6)>
Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

Great. Those changes will go into the existing slides and go out in the pre-read. If you send your additional slide any time before the meeting, that will be added to the presentation deck.

If it's helpful, I've attached the slides from today's meeting.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Wednesday, November 18, 2020 2:13 PM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Johnson, Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C]
<(b) (6)> <(b) (6)>
Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike,

Thanks for the new slide. Please add "Some" to the left ("Some previous...") and right sides ("Some key points...") of the new slide.

The phase 2b proposal is terrific. I would like to have a slide for it as well. I can make one later, but not right now.

Doug

From: "Santos, Michael (FNIH) [T]" <(b) (6)>
Date: Wednesday, November 18, 2020 at 11:44 AM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)>
Cc: Maureen Johnson <(b) (6)> "Kozlowski, Mary (NIH/NCI) [C]"
<(b) (6)> <(b) (6)>
Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

Francis asked for an addition slide reminding the group of some of the previous topics that the WG/SG have discussed (prompted because he asked about some additional topics, like pediatrics, that I mentioned that we previously met to discuss).

Attached is the updated set of 2 slides for tomorrow. The first slide shouldn't be too controversial, and you can of course add color from those previous conversations if you'd like.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, November 17, 2020 10:07 AM
To: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Cc: Johnson, Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C]
<(b) (6)> <(b) (6)>
Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Great.

I was moving over the weekend and yesterday, so I didn't actually get to my computer for work until 1am. The slide only took a few minutes, so no problem at all.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Tuesday, November 17, 2020 10:05 AM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Johnson, Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C]
<(b) (6)> <(b) (6)>
Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike: Thanks, but sorry you needed to be up at 2 AM to do this! The slide looks fine. Doug

From: "Santos, Michael (FNIH) [T]" <(b) (6)>
Date: Tuesday, November 17, 2020 at 2:01 AM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)>
Cc: Maureen Johnson <(b) (6)> "Kozlowski, Mary (NIH/NCI) [C]"
<(b) (6)> <(b) (6)>
Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

Here's a draft slide for the meeting Thursday. If you'd like any changes, I have until afternoon to make them.

You're currently on the agenda for 12:45-12:55, so it's plausible that you'll end up with less than 10 mins. By Thursday there will be both last week's WG meeting and tomorrow's VCT Sub-Group meeting to report on.

Thanks,
Mike

Michael Santos, PhD

From: Santos, Michael (FNIH) [T]
Sent: Monday, November 16, 2020 10:56 AM
To: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Cc: Johnson, Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C]
<(b) (6)> <(b) (6)>
Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Great. Thanks, Doug!

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Sent: Monday, November 16, 2020 10:56 AM
To: Santos, Michael (FNIH) [T] <(b) (6)>
Cc: Johnson, Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C]
<(b) (6)> <(b) (6)>
Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike: I can do it. Thanks for the slides! (FYI: I have a conflict, but the ACTIV meeting is the higher priority.) Doug

From: "Santos, Michael (FNIH) [T]" <(b) (6)>
Date: Monday, November 16, 2020 at 10:53 AM
To: "Lowy, Douglas (NIH/NCI) [E]" <(b) (6)>
Cc: Maureen Johnson <(b) (6)> "Kozlowski, Mary (NIH/NCI) [C]"
<(b) (6)> <(b) (6)>
Subject: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

We've been asked to give a 10-min update on the Vaccines WG at the next ACTIV Leadership meeting, Thursday, 12-1pm.

Are you able to attend? I'll make a slide summarizing the last WG mtng (and by then the Clinical Trials Sub-Group meeting Wednesday will have happened). If you're not available, I can ask Kathrin, but given that she wasn't there last week it might be tougher for her to represent the conversation.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6) | fnih.org

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/23/2020 2:15:18 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Further clarification on the question just sent.

From: Pao, William <(b) (6)>
Sent: Wednesday, September 23, 2020 10:12 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Sorry — to clarify — we know there's a shortage of testing.
I mean testing of patients who are getting pneumonia specifically.

From: William Pao <(b) (6)>
Sent: Wednesday, September 23, 2020 4:04 PM
To: 'Wholley, David (FNIH) [T]' <(b) (6)>
Subject: RE: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Hi David,
Very informative meeting as usual.
I had a question maybe not related to ACTIV activities but to OWS or CDC. However, if addressed could help with recruitment on ACTIV studies.
I noticed on this CDC link that the number of deaths related to COVID-19, pneumonia, or influenza for 2020 are nearly 300,000, while the number attributed to COVID-19 only are almost 200,000,
<https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm>

To me, this suggests **many patients still are just not getting tested**. Is someone in the government addressing this? If addressed, maybe there'd be more patients to enroll in trials?

Best,
William

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> > On Behalf Of Wholley, David (FNIH) [T]
Sent: Wednesday, September 23, 2020 2:35 AM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> >; Bancel, Stephane <(b) (6)>
<(b) (6)> Carter, Kara (b) (6) >; Cavaleri, Marco <(b) (6)>
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)>
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> ; Dolsten, Mikael <(b) (6)> >; Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> ; Erck, Stan <(b) (6)> >; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> >; Freire, Maria (FNIH) [T] <(b) (6)> ; Gadbois, Ellen (NIH/OD) [E] <(b) (6)> ; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> >; Hudson, Thomas <(b) (6)> >; James, Stephanie (FNIH) [T] <(b) (6)> >; Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> >; Kramer, Lynn <(b) (6)> ; Lane, Cliff (NIH/NIAID) [E] <(b) (6)> >; Lepore, John <(b) (6)> ; Marks, Peter (FDA/CBER) <(b) (6)> >; Marston, Hilary <(b) (6)>

(NIH/NIAID) [E] < (b) (6) Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David
 (b) (6) >; Menetski, Joseph (FNIH) [T] (b) (6) ; Messonnier, Nancy
 (CDC/DDID/NCIRD/OD) (b) (6) >; Pandya, Hitesh (b) (6) Pangalos, Mene
 (b) (6) >; Pao, William (b) (6) >; Parker, Ashley (NIH/OD) [E]
 < (b) (6) Paul, Steve (b) (6) >; Perlmutter, Roger (b) (6) ;
 Plenge, Robert < (b) (6) Plump, Andy (b) (6) >; Rachel Ramoni
 < (b) (6) >; Rasi, Guido (b) (6) Reed, John < (b) (6) >; Reese, David
 (b) (6) >; Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) ; Skovronsky,
 Daniel (b) (6) Stein, Peter (FDA/CDER) (b) (6) ; Stoffels, Paul
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 (b) (6) Tsai, John (b) (6) >; Vessey, Rupert < (b) (6) ; Virgin, Skip
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Woodcock, Janet (FDA/CDER)
 (b) (6) >; Young, John (b) (6) >; Colvis, Christine (NIH/NCATS) [E]
 (b) (6) Desrosiers, Betsy (b) (6) >; Eric Hughes
 (b) (6) Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) Lowy, Douglas (NCI) < (b) (6) ; Read, Sarah (NIH/NIAID) [E] (b) (6)
 Young, John (b) (6) Bugin, Kevin (FDA/CDER)
 (b) (6)
Cc: Anderson, James (NIH/OD) [E] < (b) (6) ; Austin, Christopher (NIH/NCATS) [E]
 < (b) (6) ; Burklow, John (NIH/OD) [E] (b) (6) ; Carlucci, Dana
 (b) (6) ; Castillejos, Carlos < (b) (6) ; Culp, Michelle (NIH/OD) [E]
 (b) (6) ; FNIH Central Account (b) (6) ; Hallett, Adrienne (NIH/OD) [E]
 (b) (6) >; Myles, Renate (NIH/OD) [E] (b) (6) ; Parker, Ashley (NIH/OD) [E]
 (b) (6) ; Gorman, Greta (FNIH) [T] (b) (6) ; Hallett, Adrienne (NIH/OD) [E]
 (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6) ; Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) ; Alvarez, Rosa Maria
 (b) (6) ; Margaret Anderson (b) (6) >; Appell, Evan (b) (6)
 Chen, Helen Q. (b) (6) >; Elsaid, Olivia (b) (6) ; Gonzalez, Nina
 < (b) (6) ; Hawk, Harrison (b) (6) ; Mendelson, Jesse (b) (6)
 Menetski, Joseph (FNIH) [T] (b) (6) ; Santos, Michael (FNIH) [T] (b) (6) >; Stratton, Benjamin
 (b) (6) >; btolman < (b) (6) ; Tountas, Karen (FNIH) [T] (b) (6)
 Wachtel, Jonathan < (b) (6) ; Wholley, David (FNIH) [T] < (b) (6) >; Melencio, Cheryl (FNIH)
 [T] (b) (6)

Subject: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from **9:00 – 10:00 AM Eastern U.S. time tomorrow**, Wednesday September 23. I have also attached notes from our August 26 Leadership Team meeting as well as our last ACTIV EC meeting on September 9.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

COLL0000016903-2516954

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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Sent: 7/21/2020 7:14:01 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Pao, William [(b) (6) Stoffels, Paul [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Plump, Andrew [(b) (6)
CC: Adam, Stacey (FNIH) [T] [(b) (6) Alvarez, Rosa [(b) (6) Anderson, Margaret [(b) (6) Chen, Helen [(b) (6) Elsaid, Olivia [(b) (6) Gonzalez, Nina [(b) (6) James, Stephanie (FNIH) [T] [(b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stratton, Benjamin [(b) (6) Tolman, Brett [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [(b) (6)]; Anderson, James (NIH/OD) [E] [(b) (6) Austin, Christopher (NIH/NCATS) [E] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Castillejos, Carlos [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) FNIH Central Account [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Trea (NIH) [C] [(b) (6)]; Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Gorman, Greta (FNIH) [T] [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Peralá, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6)]; Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Hawk, Harrison [(b) (6) Lucas Smalldon [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Hardesty, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://fnih.zoom.us/> (b) (6)

Start: 8/14/2020 4:00:00 PM

End: 8/14/2020 5:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock,

**Optional
Attendees:**

Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Hawk, Harrison; Lucas Smalldon

Shortening calls to 1 hour in length.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 7/13/2020 11:21:01 PM
To: Bascles, Lionel [(b) (6)] Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6)]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6)]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6)]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6)]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Takas, Therese [(b) (6)]; Vincent, Mike [(b) (6)]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Stratton, Ben [(b) (6)]
CC: Wachtel, Jonathan [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6)]; Jansen, Kathrin [(b) (6)]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]; Ardiff, Bernadette [(b) (6)]; Criffield, Robin [(b) (6)]; Hamilton, Nancy [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [bminnich@fredhutch.org]; Mueller-Reichenstein, Petra [(b) (6)]; Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora [(b) (6)]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6)]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6)]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange